

# Health Surveillance in South America

epidemiological,  
sanitary and environmental



**Health  
Surveillance  
in South America:**  
epidemiological,  
sanitary and environmental

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# Health Surveillance in South America:

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# Index

Prologue	11
Presentation	17
Introduction – Conception and Practices of Surveillance in the South American Health Systems	23
<b>PART I – CONTEXT, COMPONENTS AND HEALTH SURVEILLANCE AGENDA IN SOUTH AMERICA</b>	
Chapter I – Recent epidemiological changes in South America	41
Chapter II – Sanitary Surveillance Systems in South America	55
Chapter III – The role of Health Surveillance on the quest for safety, access and innovation boosting in medicines, medical products and food	73
Chapter IV – Risks communication in Sanitary Surveillance	85
Chapter V – International Cooperation and Interaction of the UNASUR regulatory authorities within the south american health care systems	103
Chapter VI – South American Network of Health Surveillance and Response: creation, agenda and challenges	111
Chapter VII – Disaster risk management in the framework of UNASUR Health	125
Chapter VIII – Epidemiological surveillance of non-communicable diseases	147
<b>PART II – Health SURVEILLANCE AS A SPACE FOR SOUTH AMERICAN SYSTEMS OF HEALTH’S STRENGTHENING</b>	
Chapter IX – Innovating experiences and challenges for Health Surveillance	161
Chapter X – Paths to advance: an agenda for the 21 <sup>st</sup> Century	205





## Prologue

*Jorge E. Venegas*

**H**ealth Surveillance and the Sanitary Surveillance Systems in South America pose a challenge to our countries. The demographic and epidemiological changes, specially for the morbidity and mortality patterns, as well as the technological innovations, demand an efficient and integrating response from our nations not only in the governmental and intergovernmental levels, which were created for this purpose, but also from an wide communitarian participation point of view.

The heterogeneous nature of the epidemiological profiles among the countries of the region or within them is associated with life conditions and, therefore, requires a political, economical, environmental and social focus. It is essential, therefore, to adopt measures and governmental policies towards the social determinants, giving special emphasis to the construction of the adequate physical and social environments, as well as facilitating healthier behaviours by the population.

It must be highlighted that in the last few years the development of social policies have been gaining momentum in countries around the world and in the region, and this process is a relevant shift for those nations. It has been supported by the political commitment of the states to reduce inequalities in health.

We have walked a long way in this path, which doesn't mean we didn't face hardships. Although we have accomplished a lot, we are aware that we still have many challenges to tackle in the present and in the near future.

Concerning health surveillance, the Andean Community and the MERCOSUR have been working alongside in various issues since 2005, when the International Health Regulations were approved in the World Health Organization. This means the cooperation in this area is already in place, and should be strengthened and enhanced, as evidenced with the Network of National Health Institutes, created in 2010 within UNASUR. Its objective is to underpin the research on priority health problems and on technological development.

Briefly reviewing the process developed by our countries, it is possible to point out the Andean Health Organism - Hipolito Unanue Covenant (ORAS CONHU), an intergovernmental organ that was created in 1971 by the Andean Region's Health Ministries aiming to turn health into a space of integration, to develop coordinated actions in order to face common problems and contribute to guarantee the right to health. ORAS CONHU is run by the Meeting of Health Ministers of the Andean area and has a permanent Executive Secretariat.

MERCOSUR, which was created in 1991, has bodies specialized in health. In the framework of the Council of the Common Market, the Sectoral Meeting of MERCOSUR Health Ministries has been created (RMS), which is aimed at harmonizing the health policies of the member states and associate states. RMS features Intergovernmental Commissions that approach issues such as the International Health Regulations, HIV/AIDS, dengue, drugs policy, donation and transplants, risk management, non-communicable chronic diseases, among others. It also features the Work Subgroup 11, which is part of the Group of the Market, a technical forum aimed at harmonizing the sub-regional norms in order to facilitate the free flow of goods, people and services within the bloc. The Health Surveillance Commission operates within this Work Subgroup's framework.

The Amazon Cooperation Treaty Organization (ACTO), which was created in 1978, promotes joint actions for the harmonic development of the Amazon Basin. Unlike the Andean Integration System and MERCOSUR, ACTO is aimed towards specific goals and its nature and conformation is different, as it operates through commissions. The Special Health Commission of the Amazon being one of them.

The most recent regional integration process, UNASUR, has the South American Health Council (UNASUR Health) as means of consolidating South America into a space of health integration, which contributes to health for everyone and development. It incorporates and integrates the efforts and achievements of MERCOSUR, ORAS CONHU and ACTO. In April 21<sup>st</sup> 2009, the South American Health Council's member countries put forward a health agenda that establishes five work priority areas: Surveillance and Response, Development of Universal Health Systems, Universal Access to Medicine, Health Promotion and Social Determinants, and Development and Management of Human Resources.

The South American Health Council understands health as a driving force of the human being's transformation and of the region's economic development. It bases its forms of action on agreed values, which were established in the constitutive document of November 28<sup>th</sup> 2008. One of these values highlight health as a fundamental right that is vital for a harmonic social and human development, and as a booster of integration among the nations. Fostering the reduction of existing asymmetries among the health systems, the citizen participation and a horizontal

cooperation are some of the UNASUR Health's goals. The driving principles of them all are solidarity, complementarity, respect for universality and interculturality of our nations.

Once established, the South American Health Council (UNASUR Health) decided to develop the five areas described in the Work Plan – South American Health Agenda by constituting respective Technical Groups for its implementation: the South American Work Group of Health Surveillance and Response; Development of Universal Health Systems; Universal Access to Medicine; Health Promotion and Action on Social Determinants; and Development and Management of Human Resources.

In March 2010, the Network of National Health Institutes of UNASUR was constituted with the mission of contributing to the development of health policies with scientific and technological solutions for health issues and problems within the South American Health Systems. This objective would be carried out by integrating and strengthening the National Health Institutes and counterparts in order to enhance life conditions, to reduce social inequalities in health and to improve the welfare of the South American peoples.

On July 25<sup>th</sup> 2011, the South American Institute of Government in Health (ISAGS) was created within the UNASUR framework, which ever since has been consolidated as a relevant centre of government human resources training in the region. It also acts as an important articulator and communication agent of the bloc's member states. An institute of such nature would be unthinkable twenty years ago. Today it is a reality.

This is a brief overview of the building process of health control mechanisms in our continent. Its substance, hardships, strategies, knowledge, national and regional experiences, advancements and challenges were analysed and debated in depth in the “Sanitary Surveillance Systems in South America” and “Health Surveillance” workshops. They are the bases of this book “Health Surveillance in South America”, organized by ISAGS, which plays a substantial role in consolidating and producing knowledge in the epidemiological changes in the region, as well as collaborating with the countries for the development of a regional policy in health surveillance.

In spite of the difficulties faced by our countries' health systems and also the difficulties to give effect to the adopted resolutions in different intergovernmental areas, important achievements have been attained, like the implementation of the International Health Regulations, the increase in the basic capacities to detect and respond to health emergencies and the legislation on medicines, food and tobacco control. However, there are disparities among the countries in this matter.

There are many challenges still: the implementation of the monitoring and evaluation system of the Surveillance Network; put in effect UNASUR's Dengue

Network to mitigate the impacts of this disease in the region; push forward a South American immunization programme; and implement agreed and effective strategies for the prevention of non-communicable chronic diseases.

The development of risk communication strategies for controlled products by sanitary surveillance authorities and disaster risk management are issues that must be addressed without delay. Also in the agenda are: the international certification of the industry of strategic health products outside the region; the regulations and evaluation of technologies; and the incorporation, certification and quality control of medical devices.

On the other hand, we are aware that the sustainability of the Health Surveillance Network requires the continuous training of human resources, which is a widespread problem in our countries, where the human resources issue is highly sensitive and needs sound actions to reverse a process that undermines both the quality of our health systems and the integration we aspire. So as to integration, it is of paramount importance the identification of the needs and existing capacities in different nations.

Acting on the social determinants of health and on the non-communicable diseases is a relevant challenge in our countries. These diseases account for 76% of all deaths registered between 2007 and 2009 in the Americas<sup>1</sup>. As a bloc, UNASUR has acknowledged this issue, as presented in the 64<sup>th</sup> World Health Assembly. Taking into consideration the risk factors and the health determinants, UNASUR enabled the creation of a technical group on these subjects and on health promotion, favouring the joint work at a regional level to address problems such as overweight and obesity epidemics, diabetes, hypertension, and high cholesterol.

Each and every country in this region is committed to fight poverty. And the poverty at issue is worse still or sees its condition deepened when one goes through a non-communicable chronic disease.

We have been working thoroughly to guarantee the access of all citizens, men and women, to medicines, as we consider them a social good and its access a *sine qua non* condition for a full exercise of the right to health. Therefore, we place health above commercial interests.

In order to be successful in the fight against the chronic non-communicable diseases, the State needs to be the protagonist, coordinating all the sectors and enabling promotional and regulation measures. The Framework Convention on Tobacco Control has already given us important inputs in this matter. It is necessary then to replicate it, providing healthy environments aimed at increasing the level of physical activity and fostering an adequate diet.

The Millennium Development Goals have shown that when clear, defined and easy-to-communicate objectives are set, it is easier to establish alliances and develop

cooperation frameworks to produce concrete results in terms of health. In this sense, it seems to us that it is a political priority to agree upon clear objectives and concrete goals on these diseases at a global, regional and national level. No health system is sustainable if it works primarily on disease and not with epidemiological surveillance, prevention and promotion.

It is also challenging for the Americas the demographic and epidemiological changes that stand for our ageing population. According to Pan-American Health Organization's estimates, in 2020 the American will have 200 million elders, almost twice as much as in 2006. More than half of these will be in Latin America and the Caribbean. In 2025, 69% of those born in North America and 50% of those born in Latin America will live over 80 years of age.

These estimations evidence the last century's great successes in public health, and also involve the high costs associated with ageing, which include an increase of chronic non-communicable diseases, disabilities and other conditions related to age. Experts find that promoting a "healthy ageing" can help the countries face these challenges.

The horizontal cooperation action on, human and material resources are of vital importance to our nations in these issues. Solidarity is not to be thanked for, but to be given back: building in health issues is a solidarity action.

Similar to democratic processes that are not decreed, but constructed, our countries must keep constructing a surveillance system to serve our citizens.

Epidemiological surveillance is, by definition, "the continuous, timely and trustworthy systematic collection of relevant and necessary data on certain health conditions of the population. The analysis and interpretation of these data must provide a basis for decision taking, as well as being used for its dissemination"<sup>2</sup>. In other words, surveillance contributes with information for decision-making and, therefore, surveillance is action.

All the efforts carried out by our nations in health, all the actions that push forward and all the tools that are implemented will allow us to strengthen solidarity, joint work and union of our peoples, taking in consideration that the countries and the region grow as the welfare of our population is increased.

There are very substantial thoughts that transcend conventional thinking. We must meditate on how they serve to people, whose dignity, right to health and freedom, must be the final goal. Isn't it the time to resume the debate on what world we want? Isn't it time to deepen this debate? This is what this book is about.

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## Presentation

**W**hen ISAGS was opened in July 2011, the Workshop on “South American Health Systems: challenges for universality and equity” was one of the activities carried out. The workshop was elaborated out of a document, which contained eleven dimensions that should facilitate the works, harmonizing and integrating the presentations of the region’s different countries. One of these dimensions was “Health Surveillance”, constituted by sanitary, epidemiological and environmental surveillance, and according to what was considered by the document.

Among the various consequences of this workshop, we can point out the establishment of ISAGS Publishing House and its first book “Health Systems in South America: challenges for the universality, the integrality and the equity”. The workshop’s final assessment concluded that the dimensions aforementioned, especially sanitary surveillance, had not been addressed accordingly, as the issue’s importance is growing in the continent. Thus, a proposal for having workshops on health surveillance and sanitary surveillance was presented and approved.

The proposal was ratified in the first meeting of the Consultative Council of UNASUR, which elaborated a schedule for technical events. Therefore, the Workshops on Sanitary Surveillance (October 2011) and Health Surveillance (November 2011) were elaborated out of the detailed original dimension and as the countries deepened and validated the issues primarily formulated. On the other hand, the decision to publish this book was taken after these workshops, and it matched both ISAGS’ publishing policy and the sound understanding of the need to seek expansion and dissemination of knowledge on the South American countries’ surveillance<sup>1</sup>. The alarming lack of specific literature is evidenced in the introductory chapter “Concepcion and practices of health surveillance in the South American Health Systems” when the expression of bibliographic search is “sanitary surveillance”.

The book “Health Surveillance Systems in South America” revisits some of the many possible and necessary themes approached on the issue. In the prologue, the author, former Minister Jorge Venegas (Uruguay), highlights the huge challenge for surveillances of following up the changes in the epidemiological pattern as reflected in morbidity and mortality indicators, as well as the fast incorporation of the technological innovations. A political, economic, environmental and social approach is considered fundamental to the UNASUR countries can face the current challenges, as well as those coming up in the near future. The author concludes with a call for the union and solidarity of the peoples, and for the joint work on the welfare of the South American peoples.

In the Introduction, Gerluce Silva and Jairnilson Paim (Brazil) go through concepts of surveillance in health as means to understand the complexity out of the first ideas of systematic information registry on morbidity-mortality used to plan control actions. The term’s multiple meanings in our America comes out in the use of bibliographical science and in the definition of search terms while establishing a relationship with public health.

In the first chapter, Maria Gloria Teixeira and collaborators describe positive impacts of science and innovation to the field of public health. Associated to the advances in the continent’s social and economic conditions, mortality and fertility indicators have dropped, especially in the second half of the 20th century. The advances are abundant in South America (even though widely insufficient), and the continent is already charged with the double burden of disease, which means a prevalence of non-communicable diseases, and an important presence of new and old infectious and parasitic diseases. HIV, dengue fever and tuberculosis are some challenging examples in many of our countries.

In the second chapter, authors Ketty Sacoto Aizaga and Diego Obando Cevallos (Ecuador) display a panorama of sanitary surveillance based on the member countries’ presentations in the Workshop on Sanitary Surveillance. Legal frameworks, various concepts of public management and the State’s regulatory role, as well as the advance of the neo-liberal State, are present in the establishment of the field within collective health of eminently public nature.

Then, security, access, innovation and risk issues are discussed relating the products that are submitted to the State’s sanitary control. Therefore, third and fourth chapters are on these issues. Authors Roberto Lede and collaborators (Argentina) describe the continent’s situation regarding classic sanitary surveillance products, drugs, food and other medical products. More than the quality of a product, it is necessary that its integrity be kept from production to customer. They describe the development of the regulatory science as a fundamental link between innovations and the actual world, as means to guarantee quality, safety

and efficiency of products and technology. Following that, authors Diana Ximena Correa Lizarazo and Natalia Milena Acosta Amador (Colombia) examine risk communication, discussing it as complex subject that is approached by distinct fields of knowledge. The interaction of three classic components of risk analysis (assessment, management and communication) is fundamental to decision-making, based on scientific considerations and with the study of all the options aimed at the best solution for the population's safety before a possible hazard. They discuss risk perception and its importance in understanding the situation. They close the chapter with the conclusion that a new paradigm is needed for UNASUR, where national differences may be gathered to identify problems and possible joint risk communication strategies in sanitary surveillance, harmonized and coherent to the needs and issues of our continent.

Finishing with issues related to sanitary surveillance, the chapter on international cooperation, developed by authors Dirceu Brás Aparecido Barbano, Ana Paula Jucá Silva and Ana Paula Barreto (Brazil), highlights the importance of following up the global economic dynamics with the expansion of markets and of the diversities of producing countries, especially in what concerns medical devices and new drugs. Various sanitary accidents of global scope strengthen this point, and direct to a strengthened UNASUR, working jointly on strategic issues. In this sense, the previously mentioned search for a joint risk communication. Besides, other joint definitions carried out by the continent country's bloc turn out to be very important in the coming years. Examples of issues that can be worked jointly are joint inspections, training of human resources and credibility rendering of public institutions.

The sixth chapter, by Eduardo Hage Carmo and collaborators (Brazil, Peru, Uruguay and Argentina), is about the conformation of UNASUR Health's South American Network of Health Surveillance and Response. It starts from the integrated activities under development between the Andean Network of Epidemiological Surveillance and MERCOSUR's Commission on Health Surveillance until the constitution of UNASUR's network, all the issues dealt in this network's meetings and the actions dictated by the Five-Year Plan. The main challenges for joint work in the field of health surveillance are discussed. In particular and considering the changes in the region's epidemiological pattern, the chapter points out the need to advance in issues related to chronic non-communicable diseases, its risk factors and the establishment of common indicators. As part of the agenda related to the region's double epidemiological burden, dengue was highlighted as worth of the definition and implementation of joint strategies. As one of the strategies towards strengthening national capacities in the process of implementing the International Health Regulations (IHR), the use of tools of detection and communication of

public health events' and emergencies' communication in the region is put forward. Finally, some issues that haven't been addressed by the network yet are identified, like the monitoring and evaluation of the Network itself, public health laboratories, violence, health of workers and sanitary surveillance issues, as well as the regulation of health products and services, which are dealt in other technical groups.

The seventh chapter identifies the relevance of the issue of disasters in the region and the consequences of these events, which causes huge material and health damages, not to mention the displacement of affected populations, increasing the risk of potential transmission of diseases and generating food shortages. Also, the implications in the health services are discussed both in the affected areas when there are damages to these services, and in the areas receiving displaced populations that don't have a good service infrastructure. Katianna Baldeón Caqui and collaborators (Peru) present a review of how the disasters issue has been faced by the countries in the region and of the evolution from the focus in emergency and disaster response to the focus in disaster risk management. With this new focus within UNASUR in 2012, a network of disaster risk management has been created from a public health perspective. It has established a work plan that will be developed by the countries in the region to deal with this problem.

The eighth chapter, by Jonatan Konfino and Daniel Ferrante (Argentina), is about non-communicable diseases that represent the primary cause of death in the region, as well as its interaction with environmental, genetic, demographic, socioeconomic and cultural factors. The main health promotion strategies, healthcare and surveillance of non-communicable diseases are described. In particular, it highlights the relevance of counting on continuous or periodical data sources that permit the monitoring of risk factors associated to these diseases, like telephone and household surveys carried out in many countries. From the information gathered by these surveys, specific intervention strategies are defined and implemented, requiring a multisectoral performance. Finally, it points out the role of surveillance, which allows designing strategies, analysing and systematically redirecting its implementation, focusing the actions in vulnerable groups, and assessing its impact.

The book's second part features some existing innovative experiences in South American countries in the field of health surveillance. Initially, in the opening Workshops of ISAGS, carried out in 2011, priority issues were identified and more critical aspects for the development of epidemiological, sanitary and environmental health surveillance strategies were assessed. The countries' experiences point to simpler and innovative solutions to successfully face health risks and problems in the region. The priority issues of this publication were: a) surveillance in communities and frontier areas, through two experiences, one in Peru (Malaria

control in frontier zones in the Andean region: a communitarian approach) and another in Suriname (*Experiences and Challenges in Surveillance and control of Malaria in Suriname*); b) articulation of epidemiological surveillance and care network, also through two experiences, both in Brazil (Severe Acute Respiratory Syndrome (SARS) in Belo Horizonte: opportunity to implement surveillance in hospitals) and (The Control programmes of major endemic diseases – Dengue in Brazil).

Regarding sanitary surveillance, priority experiences were: a) Information and education for youngsters with Anvisa's Educanvisa Project (Brazil): Education in Sanitary Surveillance, an educational action, which trains teachers and professionals in the educational and sanitary surveillance areas so they can promote notions on proper use of drugs and food in the school community; b) Argentina presented, with the Anmat Observatory, the need to count on objective and trustworthy information, based on scientific evidences for decision-making; and c) Uruguay presented information management specific to the incorporation of new technologies and its monitoring through a technology surveillance project (Health technology: evaluation of incorporation and surveillance).

At last, the chapter "Paths to advance: an agenda for the 21st Century", written by the organizers, closes the book with an evaluation of the main thematic areas, conflicts and challenges for the area of Health Surveillance in South America, bringing also proposals presented in the Workshops on Health Surveillance and on Sanitary Surveillance, as well as those presented in the development of the chapters. More than that, it indicates ISAGS' collaboration possibilities for the strengthening and development of knowledge production and technical cooperation in the Health Surveillance actions in the region.

We thank all of those who contributed to this publication and, especially the organizers, the authors and ISAGS' staff for their dedication in the organization of this edition.

We hope this debate contributes in a way the countries, jointly and in solidary manner, may identify the necessary paths for the reduction of social inequalities and reach higher health levels in a sustainable way.

*ISAGS Board*

## NOTES

- I - In the beginning of 2012, ISAGS proceeded with the first discussions on the book with a group of specialists in the surveillance area for the definition of its structure and content. We would like to thank: Ana Paula Jucá (Brazil), Gustavo Gagliano González (Uruguay), Iván Allende (Paraguay), Julián Gustavo Antman (Argentina), Julieta Gandini (Argentina), Leandro Teixeira de Moraes (Brazil), Luis Francisco Beingolea More (Peru), Mónica Castro Gualano (Uruguay), Pasionara Ramos (Paraguay), Patrícia Pereira (Brazil), Percy Ocampo (Peru), Roberto Lede (Argentina), Raquel Rosa Salomón (Uruguay) and Teresita Traverso (Argentina).



# Introduction - Conception and Practices of Surveillance in the South American Health Systems

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## INTRODUCTION

**T**he various practices and conceptions in health are related with the political, economic and social conditions of time and country<sup>1, 2</sup>.

When it comes to surveillance, we can point out that in the 14th century<sup>2</sup> mortality and morbidity were used to guide control actions for health problems. One of the first examples of surveillance, as a systematic registry of information on morbidity-mortality to guide control actions, was carried out in 17th century London during the pest epidemics. In 1776 Germany, one of the features of the medical police was the systematic analysis of information<sup>3</sup>. However, such practices was only fully developed in the 19th century, and William Farr (1807-1883) is recognized as the founder of the modern concept of surveillance<sup>4</sup>.

There is no unanimity in contemporary public health and in Latin American<sup>1</sup> collective health concerning the contents and the fields of the action of what is referred as “surveillance”. Due to the existing multiple meanings of the term, a synthesis of the relevant production and analysis of its substance is a theoretical and practical need.

In this sense, this chapter is aimed at identifying how expressions such as “epidemiological surveillance”, “health surveillance”, “sanitary surveillance”, “environmental surveillance” and “surveillance of health” have been used in scientific articles in different South American countries. It also aims to analyse the various meanings these terms have. A review of the specialized bibliography featured on Lilacs and Scielo was carried out, comprehending the timeframe between January 1992 and March 2013, and the following terms were adopted in three languages (English, Portuguese and Spanish): surveillance, epidemiological surveillance, health surveillance, surveillance of health, sanitary surveillance and environmental surveillance, as well as regulations and health control.

## SURVEILLANCE AND ITS MEANINGS

### Epidemiological Surveillance

In the 20th century, various surveillance systems were developed<sup>3</sup>. Until 1950, the term “surveillance” defined the task of observing individuals and the contact of serious infectious diseases (pest, smallpox, typhus and syphilis) with the goal of detecting the first symptoms and, then, establishing isolation measures<sup>5</sup>. After the development of the Surveillance Program of the Centre of Communicable Diseases in the 1950s in the United States, the concept of surveillance began to be promoted as monitoring disease occurrence in the population<sup>6</sup>, which means “*the continuous observation of the distribution and trends of disease incidence through the systematic collection, consolidation and evaluation of the morbidity and mortality information*” (page 182-183)<sup>7</sup>. There is a clear line dividing the surveillance and intervention functions, being part of the health authority’s duties, be it the state/provincial or local, the decision and execution of the control operations.

The term “epidemiological surveillance”<sup>8</sup> is attributed to Karel Raska, and it began to be used by the World Health Organization’s Division of Communicable Diseases in 1965 to create a unit dedicated to coordinate surveillance practices. From 1968 on, when WHO turned the national and global surveillance systems of communicable diseases into a topic of debate in its 21st Assembly, such designation was internationally adopted<sup>3</sup>. Raska’s definition<sup>9</sup> (page 316) was adopted, in which epidemiological surveillance is “*the epidemiological study of a disease as a dynamic process, involving the ecology of the infectious agent, the host, the reservoirs, and the vectors, as well as the complex mechanisms concerned in the spread of infection and the extension to which this spread occurs*”.

More than incorporating activities of epidemiological research, this definition also started to be used as a synonym of monitoring and auditing. Epidemiological surveillance was interpreted as a stage of malaria and smallpox eradication programmes as well, between the attack and maintenance stages, right when a collection of residual sources was carried out. On the other hand, these programmes started to charge the surveillance teams with the responsibility of control actions in the 1960s. The expansion of the meaning of ‘surveillance’, which then began to be misunderstood as the management of control programmes and with surveillance itself, would whitewash the meaning for a useful and specific concept<sup>5</sup>.

On the 70s, WHO and the Pan-American Health Organization (PAHO) fostered the creation of Epidemiological Surveillance Systems in Latin American and Caribbean countries. Then, epidemiological surveillance was defined as a group of activities intended to collect essential information in order to unveil the diseases’ natural history, and detect or prevent any changes resulting from the

modification of conditioning factors. It is aimed at recommending timely measures for the prevention and control of diseases. It was supported by an information-decision-control system based on epidemiology and statistics, other than biological subjects and not limited to communicable diseases. Notwithstanding this wide conception promoted by PAHO, the systems were centred on infectious diseases and were associated with proposals for enhancing the performance of the Expanded Programme on Immunisation. Once again, surveillance was associated with control action. Additionally, depending on the health system's structuring and development conditions, the surveillance organs were encouraged to take a role or participate on control activities<sup>10</sup>. Likewise, in many countries, particularly those of North America and Europe, differently from what was recommended by WHO and PAHO, surveillance didn't include control measures in their concept or practices<sup>11</sup>.

In Brazil, right after the presentation of these concepts in the 5th National Health Conference, Law 6.259/75 on the organization of the country's health system was approved. Law 8.080/90 organizes the Unified Health System (SUS)<sup>12</sup>, although inspired on the definition suggested by PAHO<sup>10</sup>, focused on damage control. Therefore, the reorganization of the system also comprehended risk and social-environmental determinants control<sup>13</sup>. Currently, we may distinguish a "traditional" epidemiological surveillance from a "modern" one, also known as public health surveillance. The former corresponds to practices carried out on the daily actions of the services, like notifications, research, data consolidation, and adoption of prevention and control measures which refer to communicable diseases. The latter underpins activities of collection, analysis, interpretation and dissemination of data and information, as well as the execution of prevention and control actions focusing specific results<sup>14</sup>.

However, the use of the expression 'epidemiological surveillance' in South America is associated, in general, to articles related to infectious diseases, in spite of the existence of research on other events like child<sup>15</sup> and maternal<sup>16</sup> death, pesticide intoxication<sup>17,18</sup>, mental health<sup>19,20</sup>, violence<sup>20,21</sup>, environmental health<sup>23</sup> and risk factors for chronic diseases<sup>24</sup>.

## Health Surveillance

At the end of the 1980s, the use of the expression 'epidemiological surveillance' started to be questioned as it hindered the understanding of surveillance's scope within public health practices. It caused confusion with epidemiology as a subject and with the employment of the epidemiological logic in the health services<sup>11</sup>. Thus, the international literature has seen the term epidemiological surveillance being replaced by *public health surveillance*<sup>3</sup>. Nonetheless, the expression epidemiological surveillance is still frequently used in European, Asian and Latin American countries<sup>14</sup>.

In Brazil in the 90s, health surveillance was dealt from distinct theoretical approaches<sup>14</sup>. One of these approaches understood health surveillance as the expansion of the sphere of action of the National System of Epidemiological Surveillance beyond communicable diseases<sup>25</sup>. The other approach understood Health surveillance as the sum of epidemiological surveillance and sanitary surveillance<sup>26</sup>, which was adopted by the state/provincial or municipal secretariats to name units responsible for the respective tasks (including also the public health labs and worker's health), unified under the same sector after the administrative reforms<sup>27</sup>.

As mentioned, the concept of health surveillance doesn't include control measures in many countries' literature. However, there is a clear link with an intervention in public health<sup>28,29</sup>, such as the strong relationship between surveillance practices and responses to the detected problems<sup>30,31,32</sup>. Therefore, surveillance and actions in public health are seen here as interdependent processes<sup>33</sup>.

The debate in Brazil has brought back the issue of incorporating or not the interventions in the definition of surveillance and of these interventions' scope. According to Silva Junior<sup>25</sup>, the dilemma of information for action or information and action wouldn't exist because, although it isn't the model adopted in other countries, the concrete surveillance practice adopted in Brazil has arisen historically from the inclusion of control actions into its field. Thus, the modern concept of health surveillance can be illustrated by ordinance 1.172 of June 15th 2004<sup>34</sup>, which structured the National System of Surveillance in Health (SNVS). It included other than the communicable diseases, the surveillance of non-communicable diseases, damages and their risk factors, the environmental surveillance and the surveillance of the health situation.

More recent normative acts<sup>35</sup> in Brazil define health surveillance as *"the permanent analysis of the population's health situation, articulated with the group of actions aimed at controlling determinants, risks and damages to health of populations living in certain territories, assuring them integral attention, which includes both an individual and a collective approach to health problems"*. Therefore, health surveillance would be made up by actions of health promotion of the population, surveillance, protection, disease and damages to health prevention and control. It includes the group of surveillances (epidemiological in environmental health, of the health situation, of the worker's health and of the sanitary surveillance).

In the other South American countries, the review of the literature indicated that the adoption of the term 'surveillance in health' would be related to articles<sup>36-45</sup> that took for granted the definition put forward by Langmuir<sup>7</sup>: the systematic collection, analysis and interpretation of essential health data for the public health practices, integrated with a timely dissemination of information for interventions/actions. It means a public health surveillance. In Colombia, for example, there is

the National System of Public Health Surveillance – Sivigila, which was created to provide systematic and timely information on events that affect health in order to:

*“(...) guide policies and planning in public health; take decisions for the prevention and control of diseases and risk factors in health, optimize the follow-up and evaluation of interventions, rationalize and optimize the available resources and achieve effectiveness in actions of this nature, tending towards the protection of individual and collective health.”* <sup>46</sup>

In fact, the concept of health surveillance adopted and the priority for a determined object end up conditioning its objectives. Whilst the public health practice in its origins take as object the infectious diseases, as time passed it began to approach various conditions in many countries<sup>3,5,11</sup>. Therefore, in the last few years, an effort for establishing and developing a surveillance capacity for the chronic non-communicable diseases (NCD) has been witnessed<sup>39,47,48</sup>. The replacement of the term epidemiological surveillance for the term public health surveillance seem to have happened in parallel to the expansion of these practices<sup>14</sup>. The proposed object would be the systematic description of patterns of disease and health related events emergence in order to guide the necessary intervention’s planning, execution and evaluation aimed at controlling or preventing. In the case of non-communicable diseases, it would be to monitor its prevalence behaviour and its risk factors, so measures of health promotion can be recommended<sup>49</sup>.

Regarding organization and management, the concrete conditions of each country condition the conformation space of public health surveillance practices, whilst establishing the limits and possibilities between the regulations carried out by the centre of the system and the local-level autonomy and responsibility. In the South American federal countries, the long history of centralization on the federal level is reflected in health. Historically, the federal manager takes on a role of coordinating and normalizing within the national systems of surveillance in health<sup>25</sup>. In Brazil, the decentralization of actions and resources of the national level to states and municipalities, which included the definition of responsibilities to the three levels of government, permitted the construction of the National System of Health Surveillance. It allows the communication and support among its members<sup>50</sup>.

Health Surveillance, understood as a public health practice, is considered one of the possible uses for epidemiology in the health services<sup>25</sup>. As it analyses events related to the health of populations, it has epidemiology as an essential work tool. As the interventions become part of the public health surveillance, various medical technologies start being incorporated as work resources.

It can be concluded that public health surveillance corresponds to a modernizing dimension of the traditional epidemiological surveillance, as it expanded its object. It is a technology employed in public health as means to subsidize decision-making on prevention measures and control of health related events (risks and damages). Likewise, it also recommends actions of health promotion<sup>14</sup>.

### Sanitary Surveillance

In Brazil, a field of practises called sanitary surveillance was constituted. It is responsible for intervening on risks and sanitary problems arising from the production process and consumption of goods, from the provision of services of health or environmental interest, and taking on “*a group of strategic actions in the health system with the function of regulating, from a health perspective, the activities related to the production/consumption of goods and services of health interest, its processes and environments, be them public or private*”<sup>51</sup> (page 12).

Acting especially on risks, its fundamentals lie on biomedical, legal and epidemiology knowledge, with the support of public health laboratories. It is aimed at regulating and inspection of the production, distribution and consumption of products and services that are damaging or potentially damaging to health. Thus, sanitary surveillance is defined by the Brazilian legislation<sup>51</sup> as (page 12):

*“[...] a group of actions that can eliminate, decrease or prevent risks to health and intervene in the health problems arising from the environment, the production and the movement of goods, and the provision of health related services, including the control of consumer goods that, directly or indirectly, are related to health, taking into consideration all the stages and processes from production to consumption; the service provision control that is directly related to health.”*

Since the creation of the Health Surveillance Agency (Anvisa), the first regulatory agency in Brazil dedicated to social policies<sup>52</sup>, attempts to include health promotion into its actions, which are currently concentrated in protection, has been observed.

Sanitary surveillance is an emerging issue in the Brazilian collective health research area, as a consequence to the cooperation between Anvisa and academic institutions<sup>53</sup>. The increase of specific scientific production<sup>54, 55, 56</sup>, shows a wide structuring and strengthening of this field in Brazil. In the academy, a certain theoretical-conceptual collaboration has been developed, taking as reference the theory of health workflow, particularly its components or moments, and taking into consideration its objective: object, working resources and activities.

From this perspective, the objective of sanitary surveillance takes life quality as its reference, so the object of its practices may be characterized as “life resources”,

which would include nutrients, energies, water, air, environments, medicines, tools, food, health technologies, among others. It would involve, for example, risk control of different areas: occupational, iatrogenic, institutional, environmental and social. Therefore, the objects of action of these practices present great diversity out of the expansion of the production of goods and services and the large amount of risks associated to it<sup>57</sup>.

In order to control these risks, the exercise of police power, a group of intervention technologies or action tools are set off: legislation (legal and technical norms), assessment, inspection, monitoring, laboratory, the surveillance of adverse events and other damages, the epidemiological, laboratory and other modalities of research, and the actions surrounding health information, communication and education<sup>51</sup>.

Based on studies on the technological organization of work in health<sup>58,59</sup>, the analysis of elements in the practice related workflow could contribute to a better understanding of the various concepts of surveillance. The means to attain the objectives and expected goals may differentiate the different practices.

Analysing the specifications of sanitary surveillance objects, products, processes and health related environments stand out. Among other work resources, knowledge, tools and technical and legal rules can be considered. On the other hand, the work itself includes lab analysis, product registration, sanitary inspection, surveillance of adverse events, sanitary control of conveyance, cargo and people of transportation, and others. In this case, the work agents are State employees, the product of the work would be the control of real and potential risks, and the final goal would be the defence and protection of the collective health<sup>60</sup>.

Recent studies and renovation efforts in Brazil's sanitary surveillance point out the integrality issue as a challenge, and there are proposals of attention models from this perspective<sup>61,62</sup>. Anvisa itself recognizes sanitary surveillance as a subsystem of Unified Health System (named SUS), which means it shares its principles and directives. It also recommends its services are integrated to actions and programmes of SUS.

Finally, it is worth to highlight there isn't a universal designation for this area, which in Brazil is assumed as Sanitary Surveillance, whilst in other countries other expressions are adopted like sanitary control or health regulation. There is one variation in the organization of the services that carry out these activities, according to the characteristics of each society<sup>51</sup>. In certain countries, sanitary control is carried out through an agency or sectoral management. An example is Argentina's National Authority of Medicines, Food and Medical Technology (ANMAT), a decentralized organ created in 1992<sup>63</sup>. In other countries, the control is carried out in a more decentralized way, and it generally excludes the control of health services<sup>61</sup>.

Reviewing publications of South American countries, except Brazil, articles<sup>64,67</sup> that use the term ‘sanitary surveillance’ to designate practices of public health surveillance were identified. However, no scientific article related to regulation practices and sanitary control was found.

### **Environmental surveillance**

In the last few years, Health Environmental Surveillance has been incorporated into Brazil’s public policies<sup>68,69</sup>, which is understood as “*a group of actions that enable knowledge and change detection within determining and conditioning factors of the environment which interfere in human health with the goal of identifying prevention and control measures to environmental risk factors related to diseases and other damages to health*”<sup>35</sup>.

The specific object of these practices is the exposition understood as an attribute of a group of complex relations between society and the environment, which means investigating the group of environmental factors that act upon the population and the social relations that structure these factors<sup>68</sup>. Some work resources should be highlighted, such as: the cartography mapping and risk evaluation, the epidemiological approach to environmental issues, taking intersectorality and interdisciplinarity for granted. The development of specific life quality related indicators, associated to the quality of air and water, the noise level and others, is necessary for monitoring the particular contexts in which the risks appear<sup>68</sup>.

In other South American countries, scientific articles related to the surveillance of intoxications by pesticides were identified<sup>17,18</sup>, as well as one on the environmental health policy that presents results of a research in Colombian cities. Here, the emphasis was on atmospheric contamination and it was an initiative of the National Council of Economic and Social Policy<sup>23</sup>.

### **Surveillance of Health**

In Brazil, after the creation of SUS, a proposal of surveillance was elaborated with a focus on a model of integrated and decentralized care, comprehending the control of causes, risks and damages<sup>70</sup>. It took the continuous confrontation in a determined territory as object of the health problems, articulating actions aimed at overcoming the dichotomy between collective practices and individual practices<sup>71</sup>.

The proposal of repositioning the health practices at local level was called surveillance of health. Thus, thinking and acting to face the health problems was under the responsibility of the local level, within the governability sphere of municipal management and of health districts<sup>71</sup>. It would require refining the government capacity of the local teams in epidemiology and planning, so more adequate health situation analyses could be carried out with the identification, problem explanation and decision making for the adoption of pertinent actions.

Authors, who understand surveillance of health as a certain technological organization of work in health oriented towards cause and risk control and articulated with a project of sectoral reform, also understand as its object selected health problems that must be fought in a continuous way within a certain territory. In this sense, spatial distribution, the relationship between the ways of life of different population groups and the various expressions of the health-disease process must be considered<sup>70,71</sup>.

Interventions on the problems would be organized in operations with emphasis on intersectoral articulations, implicating new actors as agents and the participation of the civil society<sup>72</sup>. Thus, the operationalization of surveillance of health has gone through the following steps in the local level: micro-location of health problems within a territory; intervention on the population scope focused on epidemiological knowledge; acquiring information on the territory-process through territorialisation workshops; use critical geography and planning, and local health programming.

For the evaluation process and its operationalization, a logical model with different levels, dimensions and components was built, considering the complexity of intervention objects and its possibilities of transforming social practice. In this model, life conditions are highlighted, including health determinants and conditioning factors, relating these with the health needs and problems according to a cause, risk and damage control perspective<sup>73</sup>.

By understanding surveillance of health as a technological mode of organizing health practices, the use of epidemiological knowledge is raised a immaterial technology for the organization of the workflows of health services and systems. It is, therefore, a fundamental planning and management tool for health<sup>71</sup>. According to this concept, the other surveillances (public health surveillance, sanitary surveillance and environmental surveillance), like other medical-health practices, would be technologies to be used according to the problems that must be faced in attaining its specific and fragmented response<sup>74</sup>. Thus, whilst acting in determined territories, Surveillance of Health can articulate organically with primary health care, which is understood as the first level of the health system. The progressive incorporation of this technological mode of intervention by Brazil' Family Health Strategy suggests a great potential for the development of care models oriented by integrality principles.

In summary, surveillance of health is *“related with studies of social determinants of disease and represents a technological mode of organization of health practices with the incorporation of a group of actions aimed at addressing selected problems of a certain territory”*<sup>14</sup> (page 2472).

Although this technological intervention mode, which is called surveillance of health, is still not prevailing in South America, countries like Ecuador already acknowledge the need to shift the surveillance focused logic to a participative local-level monitoring as an assessment tool centred in strategic planning and in the management's collective control<sup>75</sup>.

## FINAL REMARKS

The development of health systems in the South American countries in the past decades have enabled the growing use of epidemiology in the health services as means for the identification and quantification of the population's health problems and needs, so as to guide the rational intervention on these, as well as evaluating the effectiveness of health actions, services and programmes.

Concepts like damage, risk, vulnerability and social-environmental determinants have been used in the analysis of the health situation and have brought about innovations and technologies for its incorporation in the health systems, which foster a certain technical-health rationality in decision-making. In this sense, the evolution of epidemiological surveillance systems towards systems of health surveillance encompassing the notions mentioned above, such as rationality, have enabled the region's countries to organize their health systems in a way it faces the great challenges arising from new epidemiological, demographical and socio-sanitary profiles.

The workflow in health theory permits the understanding of technologies as work resources acting upon socially defined objects. Likewise, the goals of health services and systems change over time according to each country's culture and political and social organization, not to mention international influences. Consequently, technologies cannot be seen as a decontextualised, ahistorical, depoliticized, enthroned and isolated factor<sup>58,59</sup>. They express social, economical, political and ideological relations as they can be redefined due to changes in such relations.

As these action proposals, like surveillance and sanitary control, are institutionalized, they go through changes given the different natures of public and universal health systems or market-driven segmented health systems. Raska's and Langmuir's concepts of epidemiological surveillance, as summed up previously, illustrate well such distinction. In the same way, the inclusion of control actions in the various levels of organization differentiate health systems that adopt epidemiology as a work tool from those that reduce it to a simple epidemiological intelligence service with no commitment to intervention.

From this perspective, the organization of health surveillance systems and the adoption of a model of surveillance of health in the local level represent promising initiatives for enhancing health conditions of the South American population.

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The background features a light blue map of South America. Overlaid on this map are several semi-transparent circles in various shades of blue, green, and teal. A vertical dark blue line runs down the left side of the page, with a short green segment on the left side of the line.

**PART I**  
**Context, Components and  
Health Surveillance Agenda  
in South America**





## I. Recent epidemiological changes in South America

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**T**he scientific and technological advances in the Public Health and medicine fields all over the world, together with the social and economic improvements of less developed regions in general, have been producing positive impacts in disease and death patterns of the populations.

These changes have contributed to a decrease of the mortality and fertility rates, as seen in developed countries from the 19th century on, which is the result of better life conditions. The consequence is a reduction on child mortality and on infectious and parasitic mortality, a raise in life expectancy and, as a consequence, the raise in the chronic degenerative disease burden, although these changes have taken its course more slowly and latter than in developed world countries<sup>1</sup>. However, contrary to the latter, in poorer countries many communicable diseases are still on the top of health statistic charts, especially on the poorest echelons.

In South America, only from the second half of the 20th century on and on the 21st century, more expressive transformations in health conditions of the populations could be noted, though there is a great heterogeneity among the countries and within them. One of the examples is Chile, which have been presenting a health profile with better health indicators than other countries in the region for quite a while now<sup>2</sup>. Notwithstanding that, although reductions in morbidity and mortality rates by infectious and parasitic diseases in most countries of the subcontinent, this group of causes began to coexist with chronic degenerative diseases and, then, with the appearance of new infectious diseases and the reappearance of diseases that had been controlled. In addition to that, following a global phenomenon, this region has been presenting a trend of growth in death for violent causes, like homicides and traffic accidents for example.

Important progresses in the main health indicators have, nonetheless, been observed in the past few decades in South America. Even in the region's poorer countries, a favourable tendency registered by traditional health indicators is clear, which demonstrates advances in this field. As a result of the public policies that were implemented, however, these results may be more or less expressive according to the country. Taking this panorama into consideration, this chapter presents the main epidemiological transformations the South American subcontinent, as a whole, has gone through recently, as well as the differences observed in the different countries. A similar procedure was used in the description of the evolution of some demographic, socioeconomic and health care indicators, which represent important determinants in the profile of disease and death of the population in the region, so as to make evident the existing social and health inequalities.

## MORTALITY PANORAMA

Since the 1990s, general mortality in the South American region has been around from 6.5 to 6.9/1000 inhabitants. Between 2007 and 2009, the highest rates could be found in Uruguay (9.3/1000 inhabitants) and Argentina (7.8/1000 inhabitants). In the last year, the lowest gross mortality rates has been observed in Venezuela (4.7/1000 inhabitants) and Ecuador (5.1/1000 inhabitants). This trend indicated the existence of differences in the age structure of the countries, as well as problems referring to death registry and notification in some of the countries. In this sense, adjusted by age, these rates then range around 4.8/1000 inhabitants in Chile and 9.6/1000 inhabitants in Guyana<sup>3</sup>.

The child mortality rate (Table 1) presented an average decrease of approximately 50% in the region between 1990 and 2010. In Bolivia, where this indicator's rate were the highest in 1990 (82.7/1000 live births), there was a 48.8% reduction. However, important differences persist among the countries. Last year, these rates ranged from 7.7/1000 in Chile and 40.9/1000 in Bolivia<sup>4</sup>. This is the evidence that the achieved reduction is very far from what is desirable.

Around 130 thousand deaths of children under 5 were registered in South America in 2009, of which 129 thousand (98.5%) were younger than 1 year of age. This situation points to the necessity of carrying out great efforts for protecting the lives of children in their first year of life, especially in the neonatal period, when around 60% of these deaths take place. However, the decrease trend of 1 to 4 year old children's mortality must be recognized<sup>3</sup>.

So as to mother mortality, a substantial decrease has been observed between 1990 and 2010 (around 30%). In spite of it, this figure was still high in the past year (104/100000 live births) in the South American region, not to mention a great

Table 1 – Child mortality rate (by 1000 live births) en the South American Countries, 1990 and 2010

Country	1990	2010
Colombia	27,8	15,8
Brazil	48,8	15,0
Chile	15,7	7,7
Venezuela	25,7	13,4
Argentina	24,4	13,0
Uruguay	20,2	9,1
Guyana	48,4	30,3
Bolivia	82,7	40,9
Paraguay	41,3	19,9
Peru	53,6	15,1
Ecuador	40,8	20,3
Suriname	44,1	26,3

Source: UNICEF, 2013

inequality among the countries. This means that Uruguay (29/100000 live births) and Chile (25/100000 live births) present levels similar to the most developed areas, whereas the region's lowest income countries, like Guyana (280/100000 live births), Bolivia (190/100000 live births), Suriname (130/100000 live births) and Ecuador (110/100000 live births) are on the extreme opposite<sup>5</sup>. However, it is shocking that even in this subcontinent's emerging countries and, mainly, in the less developed ones, the vast majority of the mother deaths are avoidable. This evidences not only poor living conditions, but also the quality and access problems of prenatal services, care at childbirth and illegal abortions. The latter, because they are illegal, are generally carried out in unsafe conditions and, therefore, end up in deaths.

Colombia, Ecuador and Brazil have presented the highest rates of mortality due to external causes in 2008 (109.1/100000, 88.1/100000 and 84/100000, respectively). Data from 2011 indicate that the (adjusted) rate of mortality due to traffic accidents was highest in Venezuela (28/100000) and Ecuador (23.7/100000), while the lowest can be observed in Peru (8.5/100000) and Argentina (10.1/100000). However, these rates are much higher than those found in the United Kingdom (3.4/100000), Switzerland (3.8/100000) and Sweden (4/100000), for example. So as to homicides, the higher risk was observed in Colombia (57.4/100000) and Venezuela (35.4/100000), whereas the lowest figures were those from Peru and Argentina (3.1 and 4.3/100000, respectively)<sup>6</sup>.

Non-communicable Chronic diseases (NCDs) have accounted for the majority of deaths in South America since the 1960s. Brazil and Argentina, for example,

notwithstanding their higher economic development level, present high death rates for these causes: 614/100000 inhabitants and 612.7/100000 inhabitants, respectively. On the other hand, Bolivia, Suriname and Guyana present the most alarming rates of death by NCDs<sup>6</sup>.

The scale of mortality due to these causes, added to its morbidity burden, has been reason of concern to public health authorities, which is why, since the beginning of the 21st century, this issue came to the centre of South American health agenda<sup>7</sup>. Diseases in this group include neoplasms and, mainly, cardiovascular diseases, which, besides the external causes, are the three main causes of death in the region.

Mortality by neoplasms among women was highest in Peru (134.1/100000) and Colombia (115.3/100000), while it was lowest in Guyana (61.1/100000) and Suriname (65.3/100000). Among men, Uruguay presented the highest rate (223.6/100000), and Guyana presented the lowest (64.9/100000). In the other countries, the risk of male death for these causes has ranged from 91.8/100000 in Suriname and 144.1/100000 in Brazil (Table 2). There is a possibility that access to health services and diagnosis facilities are factors explaining the differences among countries.

In what cardiovascular diseases is concerned, data from 2004 to 2009 in different countries in South America point out that, among women, the highest risk of death for these causes were registered in Guyana (267.2/100000 inhabitants) Paraguay (231.1/100000) and Venezuela (214/100000). Among men, Guyana (318.2/100000) stood out as country with higher risk of death by cardiovascular disease. On the other hand, Peru (155.4/100000), Chile (157.7/100000) and Ecuador (170.5/100000) presented the lowest rates. During the same timeframe, ischaemic heart diseases were the most frequent death causes by cardiovascular disease in Venezuela, both among women (96.6/100000) and men (153.9/100000); whilst in Colombia and Guyana (134,2/100000 and 115.3/100000, respectively), the indicator was higher among men. Deaths by cerebrovascular diseases were higher among men, ranging from 120/100000 in Suriname to 40.7/100000 in Peru. Among women, the highest rates were found in Guyana (84.2/100000), Paraguay (83.4/100000) and Suriname (82.7/100000) (Table 2).

On the other hand, Diabetes mellitus (DM) is another disease that has contributed to the increase of deaths by NCDs. This is a global trend due to an obesity epidemics<sup>6</sup>. In South America, DM presents higher death rates for this cause in Guyana both among men (72.5/100000) and women (77.2/100000), and the lowest in Uruguay (18.4/100000 and 11.9/100000 respectively) (Table 2).

Table 2 – Mortality rate due to Non-communicable chronic diseases by gender (age adjusted by 100000 inhabitants) in the countries of South America, in the last evaluated year

Country	Cardiovascular diseases		Ischaemic heart diseases		Cerebrovascular diseases		Diabetes mellitus		Malignant neoplasms		Chronic respiratory diseases		Year
	Fem	Male	Fem	Male	Fem	Male	Fem	Male	Fem	Male	Fem	Male	
Colombia	195,3	252,7	87,6	134,2	54,0	55,0	29,1	26,7	115,3	133,2	35,4	53,2	2008
Brazil	196,1	266,7	52,6	88,9	63,5	79,6	38,5	35,9	106,9	144,1	21,1	35,8	2009
Chile	99,0	157,7	25,4	57,3	33,9	49,7	14,8	19,8	99,4	137,5	11,1	18,7	2008
Venezuela	214	280,8	96,6	153,9	62,4	65,4	50,8	49,1	109,8	124,5	20,7	26,6	2007
Argentina	124,5	214,6	21,8	52,6	28,4	42,9	12,3	18,9	97,5	147,6	5,2	14,7	2009
Uruguay	168,6	263,1	37,5	83,5	66	80,3	11,9	18,4	121	223,6	10,4	44,3	2004
Bolivia	...	...	...	...	...	...	...	...	...	...	...	...	...
Paraguay	231,1	274,2	62,0	97,2	83,4	85,6	66,2	45,3	113,8	122,8	5,2	14,6	2009
Peru	116,6	155,4	28,4	48,3	30,9	40,7	17	18,8	134,1	141,8	10,6	15,3	2007
Ecuador	134,4	170,5	20,3	34,1	40,5	48,2	48,7	47,5	100,7	105,1	11,2	17,1	2009
Guyana	267,2	318,2	94,0	115,3	84,2	89,9	77,2	72,5	61,1	64,9	6,3	14,3	2006
Suriname	167,1	276,3	44,8	84,6	82,7	120	46,5	47,2	65,3	91,8	8,5	12,8	2007

Source: World Health Organization, Health Conditions and Trends, 2012

Even when age adjusted, mortality rates by NCDs in South America is higher in less economically developed countries, such as Guyana (735/100000 inhabitants), Bolivia (710.8/100000 inhabitants) and Suriname (696.4/100000 inhabitants)<sup>6</sup>. This indicates that, in addition to the high burden arising from infectious and parasitic diseases, these populations are being heavily charged by NCDs as well.

However, mortality rates by infectious and parasitic diseases<sup>8</sup> have been presenting a substantial decrease in the past few decades in most of South American countries. Between 1997 and 2009 only, these rates have fallen 58.6% in Chile (from 73.4 to 30.4/100000 inhabitants), 37.4% in Paraguay (from 123.2 to 77.1/100000 inhabitants) and 13% in Brazil (from 88.1 to 77/100000 inhabitants). Despite these advances in the region, this indicator's rate for Peru in 2007 still presents very high levels (145.6/100000 inhabitants), though it has decreased 17% in comparison with 1999 (175.6/100000 inhabitants). Surprisingly, Argentina has reported an approximately 30% increase in mortality rates by infectious and parasitic diseases between 1997 and 2007, yet it is much less (72.9/100000 inhabitants) than the 2007 rate from Peru<sup>8</sup>.

## MORBIDITY ADVANCES AND SETBACKS

There is no doubt that the South American population is living longer and that, although many health indicators still present high levels, a trend towards a decrease in mortality rates persists in many causes. However, the morbidity profile found in the subcontinent shows that the population is under a double burden of disease, since it simultaneously deals with chronic non-communicable diseases and new and old infectious and parasitic diseases.

Given this situation, it can also be mentioned that, also in relation with morbidity, some very positive transformations have taken place. For example, the greatest achievement in terms of Public Health in the Americas in the first half of the 20th century was the almost entire eradication of the circulation of indigenous measles<sup>9</sup>. Nowadays, this virus disease is only found in small sporadic outbreaks in indigenous populations in Ecuador. At the same time, the goal of eliminating rubella is under way, taking protecting concepts from harms caused by congenital rubella as a priority<sup>9</sup>. These two diseases are under integrated surveillance, and the goal is guaranteeing the interruption of the circulation of both etiological agents, in case they are reintroduced in then zones free of them. This is carried out alongside with national vaccination programmes, ensuring high rates of vaccination coverage in specific populations.

Table 3 – Tuberculosis incidence rate (by 100000 inhabitants) in the South American countries – 1990/2010

País	1990	1995	2000	2005	2010
Argentina	60	49	40	33	27
Bolivia	251	215	184	158	135
Brazil	84	71	60	51	43
Chile	62	38	26	20	19
Colombia	54	48	43	38	34
Ecuador	174	136	107	83	65
Guyana	89	89	104	115	111
Paraguay	66	52	49	49	46
Peru	317	242	184	140	106
Suriname	66	51	80	100	145
Uruguay	28	26	24	23	21
Venezuela	35	35	34	34	33

Source: World Health Organization: Global Tuberculosis control, 2011.

Following a global trend, tuberculosis has been on decline in South America (Table 3), where the rate was 107.2/100000 inhabitants in 1990 and this rate decrease to 65.4/100000 inhabitants in 2010, which means a 39% reduction in this timeframe. The highest rates of this disease in the last year can be found in Suriname (145/100000 inhabitants), Bolivia (135/100000 inhabitants) and Guyana (111/100000 inhabitants); the lowest rates can be found in Chile, Uruguay and Argentina (19, 21 and 27/100000 inhabitants, respectively). Notwithstanding that, the only country in which this disease still presents a trend of growth is Suriname. Although these it has been highlighted that these rates still correspond to thirteen times of those registered in some European countries<sup>10</sup>.

Malaria, nevertheless, is still a great health problem in the Amazon Region, affecting seven countries in South America. In this sense, in 2010 the highest incidences of this disease have been registered in Guyana (32.7/100000 inhabitants), Colombia (17.3/100000 inhabitants) and Brazil (13.5/100000 inhabitants)<sup>3</sup>. The latter has accounted for more than 50% of the notified cases of the disease in the region. However, a substantial reduction can be observed; in 2000 more than 615,247 cases of malaria were confirmed in Brazil; in 2010 this figure was just 267,049, which means a 56.6% reduction<sup>11</sup>.

Although five countries in South America have registered cases of visceral leishmaniasis, it is only an important health problem in Brazil due to the high lethality rates, which were around 6,3% in the last decade. From 2003 to 2008, this country responded for 95.7% of all 3,637 cases that are notified every year in average<sup>12</sup>.

Present in all South American countries through vectorial transmission, Chagas disease (trypanosomiasis), exclusive to the American continent, has been targeted by intense and effective control measures since the 1980s, which are focused in the fight against the most important vectors found in the main endemic areas. These interventions have interrupted the natural transmission of its agent, *Tripanosoma cruzi*, in vast areas situated in Brazil, Chile, Uruguay and Argentina since 2006, and also in parts of Paraguay. However, although Colombia, Venezuela, Bolivia and Guyana haven't achieved the interruption goal, the infestation levels of the households by triatomines and the number of new cases transmitted by vectors have been consistently reduced. Although some limited outbreaks occurred due to oral transmission of the *T. cruzi*, there are many evidences that the incidence and prevalence of this zoonosis is one of the achievements that South America should celebrate. Having Brazil as an example, the country presented a 5.6% prevalence in the 1970s<sup>13</sup> when it was estimated that around 5 million people were infected by the protozoan. In 2008, a survey carried out among children under 5 indicated that 0.01% of the individuals presented an infection likely to have happened through a vector<sup>14</sup>.

Among the emerging and re-emerging diseases, HIV/AIDS and Dengue must be noted, as they have become endemic-epidemic in the majority of the South American countries. According to estimates, in 2001 almost 900,000 lived with HIV in the region, and in 2011 this figure amounted to 1,057,800, representing a 15% growth<sup>15</sup>. Men who have sex with men represent the group with the higher number of people infected by the virus<sup>16</sup>. The countries with the highest number of carriers of the virus are Brazil and Colombia, representing 60% of the regional population infected, as they have the continent's biggest populations. Although Brazil has the highest number of people infected, the AIDS death rates in this country has been the lowest in the region; followed by Argentina and Venezuela in the last ten years. This can be explained by the coverage of antiretroviral therapy, which is around 60% in these countries<sup>15</sup>.

After reappearing in South America, initially in Colombia and Guyana at the end of the 1970s, Dengue has presented intense transmission strength. By the 1990s, it had become one of the most important public health problems of the region, in terms of communicable diseases. In 1998, dengue fever epidemics by the four virus's serotypes, including Haemorrhagic Dengue, reached nine South American countries, with an average incidence of 205.46/100000 inhabitants. The situation worsened in the following decade, when 6,786,771 cases were notified to PAHO. In 2010, there was an incidence peak at 389.5/100000 inhabitants. The huge size of dengue fever epidemics causes a substantial increase in the demand for health services and in school and work absenteeism, specially in the biggest and most important urban centres. In addition to that, an increase in the absolute number of cases of dengue, from 35,113 (1995 to 1999) to 95,836 (2006 to 2010), can be observed, especially of Haemorrhagic Dengue fever and Dengue Shock syndrome, which present very high death rates (around 1.9% from 2006 to 2010)<sup>17</sup>. In regards to investments in control measures aimed at the chemical, physical and biological control of the main vector of the dengue virus, there hasn't been an epidemiologic impact over this disease. Brazil stands out in this scenario as it has 80% of the notified cases in South America, and as it spends annually over one million dollars in surveillance and control actions for this disease<sup>18</sup>.

The NCDs incidence and prevalence have been increasing as the elderly population grows and because of modern lifestyle, and other factors such as overweight, obesity and other health problems. So as to risk factors, it must be noted that the estimates of annual alcohol consumption in South America are very high, led by Brazil with 10.1 litres per person; whilst the lowest level of consumption is found in Bolivia with 5.8 litres per person<sup>6</sup>. Even when these levels are lower than those found in European countries, where it can go up to 16 litres per person, as in Russia, the abusive use of alcohol in the South American region has been possibly

damaging the population's health, other than the social problems typical to this habit. On the other hand, tobacco consumption by people over 15 years of age reaches 35.7% in Chile and 31.3% in Uruguay<sup>6</sup>.

The morbidity burden by the NCDs can also be seen, for example, by the prevalence of hypertension in people over 25, which, age-adjusted, in 2008 got to 42.5/100000 inhabitants in Chile. The lowest is found in Peru, where it is 34.3/100000 inhabitants<sup>6</sup>. This disease is an important cause for hospitalization as it frequently causes serious consequences such as ischaemic heart diseases and cerebrovascular diseases<sup>6</sup>. On the other hand, following a global growing trend of obesity, Chile, Venezuela and Argentina lead the statistics with 29% of the population, a rate similar to more developed countries like the United States (31.8%)<sup>6</sup>.

The pressure of NCDs on the health services, as they demand continuous attention and, in most cases, high complexity and high cost health care, is a factor that increases social inequalities in health in the subcontinent, because access to more advanced technologies isn't equally distributed.

## **EVOLUTION OF THE DEMOGRAPHIC, SOCIOECONOMIC AND HEALTH CARE INDICATORS**

In 2010, almost 83% of the South American lived in cities. This urbanization phenomenon was determined by a rural-urban migration process that began in the 1950s as a consequence of the model of political, social and economical development<sup>19</sup>.

The life expectation at birth in the subcontinent has been increasing, so between 1980 and 2010, it went up from 65.1 to 73 years, which means an approximately eight years improvement in about three decades. In spite of this advancement, it still presents lower levels than developed countries, while an unequal distribution remains among the countries of the region. Although in Chile the life expectation at birth was 78.5 years in 2010, which is close to the level of developed countries, in Bolivia it is still 65.5 years. On the other hand, countries like Ecuador, Venezuela, Colombia and Brazil (the region's emerging countries) are at an intermediate situation, with life expectations ranging from 74 and 75.9 years<sup>3</sup>.

In the region as a whole, the population over 65 years, which was 14.7 million in 1990, has gone up to 27.7 million in 2010, which represents an 87.8% increase. Argentina and Uruguay have almost 15% of their population in this age group. In Bolivia and Paraguay, this group represents only 5% of its total population and over a third of it is under 15 years of age. These discrepancies are a reflection of the level of development of each country<sup>3</sup>.

Even though the South American countries are among those with deep inequalities regarding social and economy indicators, since 2000 it has been witnessed an increase in the Gini Index among the majority of countries. The only exception was observed in Uruguay, whose index was stable varying from 0.44 to 0.45<sup>20</sup>. The most impressive advancements were seen in Ecuador, Argentina and Peru. A research carried out by the World Bank, which included Argentina and Brazil, has attributed these advancements to two factors: progressive income transferences implemented by the government, and a downtrend in the salary of less qualified workers, which is a phenomenon associated with an increase in the supply and consequent reduction of specialized workforce<sup>21</sup>.

The Gross Domestic Product (GDP) per capita presented an increase in all South American countries since 1990. It was more substantial in Guyana, where it went up from USD 780.00 in 1990 to USD 3,460.00 in 2010, yet it still is very far from the levels of other countries in the region. In the same year, the highest GDP per capita in the region was from Argentina and Chile (over USD 15,000)<sup>22</sup>.

The Human Development Index (HDI) has also been increasing in the continent since 1990, when it was less than 0.600 some of the countries (the lowest was 0.489 in Guyana and the highest was 0.698 in Chile). In 2011, Guyana's index rose to 0.633, Chile rose to 0.805 and other eight countries (73%) already presented over 0.700 in the HDI levels. That means that in the last year there was no country with very low HDI levels and 25% (three countries) already presented levels that are considered of high development<sup>23</sup>.

Public expenditure in the health sector has been increasing in all of the countries in the region, especially Argentina, Uruguay and Chile. However, healthcare coverage varies from country to country, and it is higher in Chile, Venezuela and Brazil. In the latter, the public system is universal, while in Chile 13% of the population has no kind of health insurance<sup>3</sup>.

## FINAL REMARKS

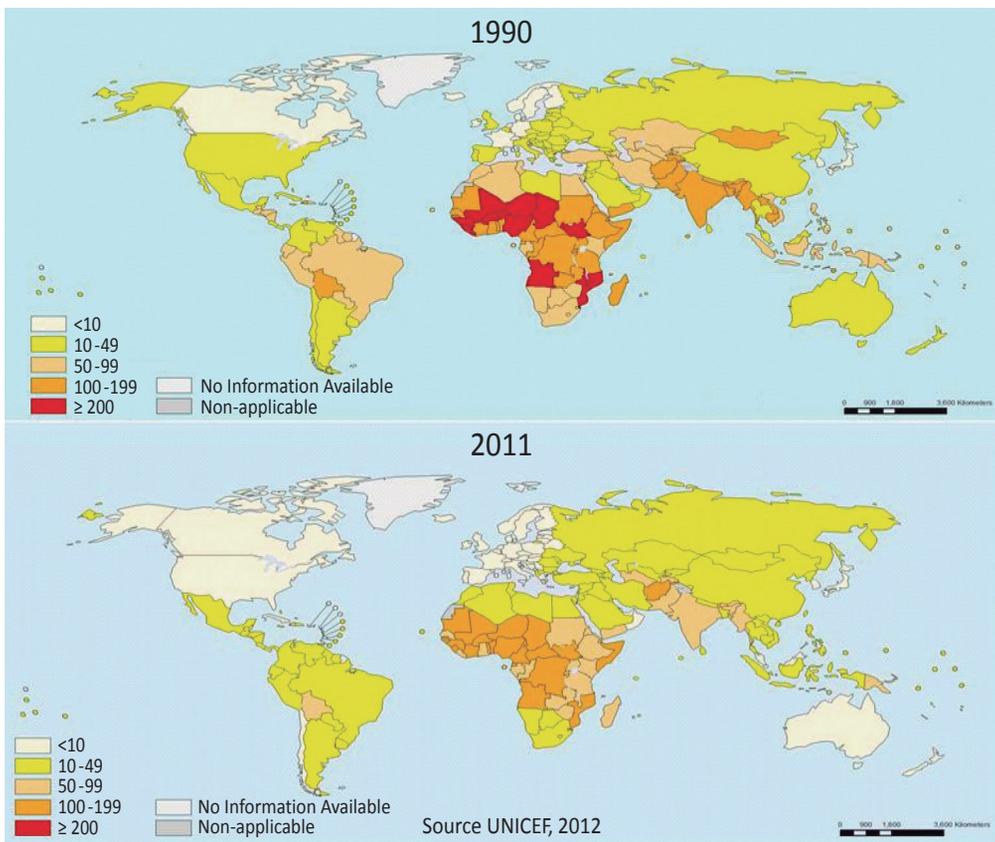
The last few years have been a period of important changes for South America, and resulted in substantial improvements in economic and social indicators. The effects of these advancements can be seen in the trend presented by the level of various health indicators, as they are important determinants of the conditions of the populations' lives and health.

Although there are limitations in the quality and coverage of the systems of information on morbidity and mortality, which vary from country to country, the lack of uniformity in the attained progresses, in addition to some discrepancies between different sources of information that were consulted, it was possible to

outline the development of the epidemiological situation in the recent years, as well as to note the progresses made.

By considering the hardship some of this region's countries have been facing while comparing their social situation, specially their epidemiologic situation, with other countries in the world, a positive trend can be clearly seen. If we take examples of under-5 mortality and HDI, we can observe that, in the last 20 years, the level of these indicators have progressed in a such a way that South America is in an intermediate level between the situation found in the main countries of the European Union and North America and the situation found in regions and less developed countries (Figures 1 and 2). We are even closer to the former.

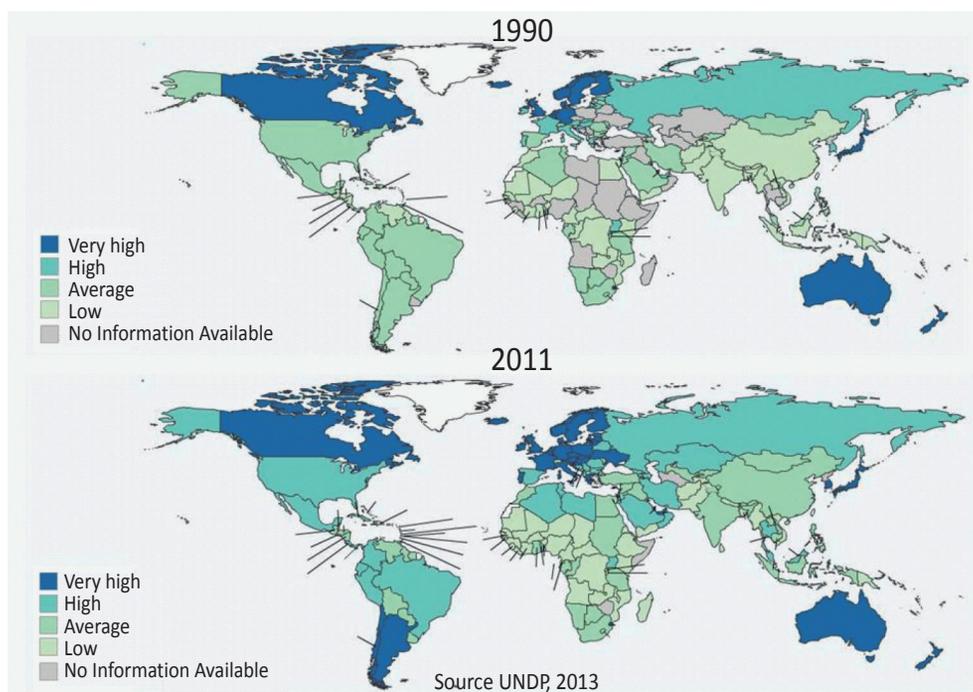
Figure 1 - Under-5 Mortality Rate (by 1.000 live births), 1990 and 2011



Although it is expected this development trend may continue in an ever more favourable way, the current times present many uncertainties. The serious economic crisis, which affects almost the entire world, is also affecting countries of the South

American continent and requires caution in the forecast of future trends. It is so because the life and health conditions of the populations are dynamic processes that depend on complex political, social and economic climate of each society. Certainly, the global scenario may impact negatively in poorer countries and in their more fragile echelons. Therefore, it is essential that each country strengthen its capacity to adopt measures towards minimizing negative social repercussions that may arise in this context.

Figure 2 – Human Development Index (HDI), 1990 and 2012



Some of the integration and mutual aid initiatives that have been adopted in South America through the constitution of blocs of countries with commercial, economic and/or political objectives include technical cooperation and a specific health agenda. They represent strategies that may enhance the continuity of improvements in the life and health conditions of this country's populations. By understanding the importance of social determination in the health-disease process, the big issue posed for the subcontinent is if the compensatory and structural policies, which may be intensified or implemented in the following years, will be able to minimize inequalities in health, as they are still very high despite the progresses achieved.

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## II. Sanitary Surveillance Systems in South America

*Ketty Sacoto Aizaga  
Diego Obando Cevallos*

**T**alking about organs in charge of sanitary surveillance in the Latin American countries involves, doubtlessly, mentioning the public management and the reforms processes in the region's health sector. Each of these processes has determined the way of organizing the State and of an institutional structure in order to materialize it. In the 1980s, Latin America saw no choice but to take neoliberal economic measures, as dictated by the Washington Consensus that, among many other stipulations, proposed the reduction of the size of the State and the privatization of public services<sup>1</sup>.

In order to enable the neoliberal proposal, it was necessary to provide the State with an institutional basis aligned with new theories of public management, as raised by the business vision of the State since the 1990s. In this context, many Latin American countries incorporated the concept of agencies in order to increase efficiency in the public management of various sectors. As regards to health, and specifically as regards to sanitary surveillance, agencies have been organized in a decentralized manner, with economic and financial autonomy, and jurisdiction over the entire national territory to operationalize control and surveillance actions of products that are subject to health registry and compulsory health notification.

The technical-interpretative references and frameworks to analyse the functionality and pertinence of this way of organizing public management are various, since the "institutional adjustment" was distinctively shaped from country to country and varied according to the level strictness each exerted in applying the model and the structural adjustment measures<sup>1</sup>. This aspect, despite its relevance, will not be analysed in this chapter.

Organizing health surveillance needed a conceptual delimitation and a typology that succeeded in covering the diversity of environments susceptible to surveillance and control. Although the existing bibliography on health surveillance marks its

relationship with epidemiologic surveillance<sup>1</sup>, some country's legislation, such as Colombia's, clearly defines its differentiation from sanitary surveillance. The Colombian National Health Plan presents health surveillance as:

*"...the group of systematic and constant processes of collection, analysis, interpretation and dissemination of information, and of research for the identification of health needs of the population and for the service's response to improve health and life quality (...)"<sup>2</sup>.*

So, it considers that this category is made of processes: public health surveillance, health surveillance in work environments, sanitary surveillance and surveillance of the management of the General System of Social Security, where:

*"Sanitary surveillance monitors the risks related to food, drugs, health technologies, household products, public facilities and productive chains. For this purpose, it applies active surveillance using the methodology of best practices and research, among others (...)"<sup>2</sup>.*

The National Health Institutes are the primary institutions in charge of carrying out some kind of control over drugs, foods and water; in some cases they start as being part of the Health Ministry and in other cases they are part of more complex organs, such as agencies. Health Superintendence and Regulatory Agencies are in the framework of regulation and control organs that have been created in the region as institutional proposals in the past few decades.

One of the structural advances in the public management in Latin America are the decentralization processes, specially the so-called functional decentralization or decentralization of the management area, which transfers functions to organs with their own legal personality so as to escape the rigidity of the system and of ordinary administrative law. It includes the creation of agencies operating with autonomy in the management of resources and in the provision of their activities, carrying out accountability for attained results, having independent legal personality or not<sup>3</sup>. According to the 2009 Chilean Government's research on decentralization in Latin America:

*"In Latin America (...) there were great achievements in decentralization. However, hardships in competence superposition among different government levels persist, as some of these competencies have not been accompanied by necessary resources to be carried out. As regards to tax decentralization, a greater decentralization can be found in expenditure than in incomes."<sup>4</sup>*

The regional integration process has also played a supporting role in enhancing sanitary surveillance in the region to the point information and experiences exchange mechanisms have been established, as well as multiplication and replication processes. The strengthening of national regulatory authorities of medicines and biological products and the Pan-American Network for Drug Regulatory Harmonization (PANDRH), the decisions of the Andean Community of Nations (CAN) on food, cosmetics and hygiene products regulations are examples of regional initiatives aimed at improving the sanitary surveillance management in the southern countries, as well as guaranteeing the right to fair and transparent commerce.

As a conclusion, sanitary surveillance represents a strategic field in guaranteeing the right to health. With the diversification of the market of health products and, in general, of those for human consumption, specializing control organs and bodies are more and more needed. For this purpose, institutional proposals have been built, whose structure has not escaped from neoliberal focuses in the health management. Notwithstanding that, in the last few decades, these very institutions have been adapting to the new requirements of the Latin American states, as well as to their peculiar ways of public management. The improvements in the field of sanitary surveillance have been boosted greatly by the health reforms, decentralization and regional integration processes.

Below, experiences in sanitary surveillance are presented by each country, as seen in the Workshop on Sanitary Surveillance Systems of South America, carried out in Rio de Janeiro from October 3<sup>rd</sup> to 7<sup>th</sup> 2011. The following expositions are a summary of their presentations<sup>III</sup>.

## **ARGENTINA**

### **Presentation by Dr Roberto Luis Ledo, Planning and Institutional Relations Director of Anmat**

The national organism of sanitary surveillance of the Republic of Argentina is the National Administration of Drugs, Foods and Technological Medicine (Anmat), created by Presidential Decree 1,490/1992. It is a decentralized organ under the Nation's Health Ministry. Its objectives are as follows: carry out registration, control, inspection and surveillance activities concerning the quality of products, substances, elements, processes, technologies and materials consumed by or used in medical practices, food use, and of activities and processes mediated or comprehended in these subjects; apply and enforce legal, scientific, technical and administrative dispositions comprehended in the field of its competences.

Its competences include: health control and inspection, surveillance on the efficacy and detection of side effects, control of the activities, processes and technologies, prevention and health protection.

Its organizational structure includes two institutes and five boards: the National Institute of Food (INAL), the National Institute of Medicines (INME), the Board of Medicines Evaluation, the Board of Medical Technology, the Board of Planning and Institutional Relations, the Board of Legal Issues and the Board of Coordination and Management<sup>IV</sup>. It has 826 employees to carry out its activities, divided in administrative and technical personnel.

Anmat kept a mostly unchanged structure for eighteen years, which represented a limitation in the adaptation to new market requirements. From April 2010 on, it triggered a reorganization process in its management that was structured in the following strategies:

1. Strengthen the link with different jurisdictions of the country;
2. Foster the active participation of the professional and legal community, and create proper feedback mechanisms for recognizing and addressing issues of its competence;
3. Increase sources of institutional information to strengthen transparency in its actions;
4. Raise scientific development and technical capacity aimed at multisectoral collective establishment of regulatory rules;
5. Increase the development of international activities;
6. Fight counterfeit of products to health;
7. Respond institutionally to the increase in proceedings;
8. Respond institutionally to better protect the community.

Its strengths include: legal framework, technical training, regulatory regulations, regulations on exports and imports, risk communication, professional training, laboratorial support in medicines and food, and emergency plans in issues of its competence. Its weaknesses include: limited laboratorial support in medical products, absence of new technology incorporation, and absence of delegations in the customs. Its threats include inadequate building infrastructure. And its opportunities include: support to health policy authorities, renovation of the organization's structure, authorization to increase the staff and renovation of control laboratories.

It is important to highlight that in the international arena, Anmat is a regional reference regulatory authority for drugs, certified by the Pan-American Health Organization (PAHO).

## BOLIVIA

### **Presentation of Dr José Antonio Zambrana, Chief of Epidemiology of the Ministry of Health and Sport**

Within the Vice-ministry of Health and Promotion of the Ministry of Health and Sport, one of this ministry's functions is to register foods and beverages, and carry out the registry, control and surveillance of medicines, inputs and equipment for health.

The national regulatory authority for medicines, the Unit of Medicines and Technology in Health (Unimed) is in charge of the normative control and oversight of all health facilities of the State, decentralized or private that are specifically or intimately related to pharmaceutical and biochemical services. Other structures are the National Pharmacologic Commission and the Sub-commission for Natural and Traditional Products.

The Board of Medicines and Technology in Health (Dinamed) is constituted by various areas: health evaluation and registry, surveillance and control, supply and rational use (where pharmacovigilance is performed through a national system - SNFV); and the laboratory for medicines quality control and toxicology (Convamyt).

Governability in the pharmaceutical sector is conceived through the health policy, and is based on four promotion pillars (SAFCI model): social participation, intersectorality, interculturality and integrality, with a focus on family, communitarian and intercultural health. A process of socialization, adoption and implementation of the Ethical Framework and Conduct Code for public sector processes related to medicines is under way. Improving levels of transparency, ethical practices of regulation and pharmaceutical management in the public sector is required, as well as reducing vulnerability to corruption.

In order to implement the Ethical Framework in the different areas of Unimed, it is essential to strengthen regulatory Units of medicine and the Units of medicines acquisition.

Its strengths include: social participation (joint work, unification of criteria), management organization through strategies, work plans, programmes and timetables, clear direction on where to target its change actions (actors: society and technicians) and process of participative creation of a code of ethics. The work carried out in the prevention and promotion areas must also be highlighted, which include clear proceedings in health alerts, based on focal points that confirm the source (official), notify the Unimed-SEDES to verify it, and request Senasag-ADUANA to provide entry information in the country. If needed Unimed, then, issues resolutions, through which the health registry of the product is suspended.

If there is risk, the health registry is cancelled. The citizens are informed through different communication means. Regarding emergency plans, these count on contingency plans on how to proceed in case of epidemics or pandemics, although no technologies have been comprehended until 2009-2012.

Governability in the pharmaceutical sector is a novelty in Bolivia, so it presents some challenges, as it requires negotiation strategies with various sector and actors, who have different interests within the sector.

## **BRAZIL**

### **Presentation of Dr José Miguel do Nascimento Junior, Director of the Health Ministry's Department of Pharmaceutical Assistance**

The national sanitary surveillance system is integrated by the Health Ministry (MoH), the National Health Surveillance Agency (Anvisa), the National Council of State Secretaries (Conass), the National Council of Municipal Health Secretaries (Conasems), the Centres of State Surveillance, the Federal District and the Municipalities (Visas), the Public Health Laboratories (Lacens), the National Institute of Quality Control in Health (INCQS), the Oswaldo Cruz Foundation (Fiocruz), and the State, District and Municipal Health Councils. Anvisa as a decentralized entity coordinates the system and the surveillance actions that are developed are of educative, normative, preventive, and control character. If necessary, it carries out punitive actions.

Anvisa's mission is to promote and protect the health of the population and to intervene in risks arising from production of use of products and services subject to surveillance. It does so by coordinating its actions with States, Municipalities and the Federal District, in conformance with the principles of the Unified Health System (SUS) to improve the Brazilian population's life quality<sup>v</sup>.

Anvisa was created by Law 9,782 of January 26th 1999. It operates under a special autonomous regime, is linked to the Health Ministry, and is administratively and financially independent. Its performance goals are aligned with the Health Ministry's and regulated through management contracts.

It is aimed at the sanitary control of the production and commercialization of products and services that are subject to sanitary surveillance, including environments, processes and inputs of technologies related to it, not to mention the control of ports, airports and frontiers.

In order to carry on with the work, Anvisa has an infrastructure in ports, airports and frontiers with approximately 86 sanitary surveillance checkpoints. There are 40,000 servants in the three levels of government, 13,500 of which with

a higher degree of education. The labour status of this staff is different, as its own work force corresponds to 3,030 employees in the main area, 94.51% of which has post graduate degree (extension courses, masters and doctorates). In the past five years, Anvisa has invested a considerable sum of money in personnel training, in short, medium, and long-term courses on subjects like regulations in sanitary surveillance, management development, and also joint trainings with other regulatory agencies of the world.

Anvisa registers and controls drugs (new, biological, generic, similar, phytotherapy, homeopathy, and specific – notified as low risk), with priority to medicines that are considered to be within the National Health Policy. Thus, most of the post-registry requests are associated with generic and similar medicines, in which the domestic industry has a bigger share in the Brazilian market.

So as to food, the control model (of products and companies: registry, labelling, packaging, identity/quality, limits of contaminants, additives, Best Practices for Food Safety, quality control) is transforming from a pre-market trend to a strong post-market trend. Rationalizing the regulations tools has been carried out, mostly in terms of evaluation of regulatory impact, of deepening the knowledge on risks associated with traditional means of production, and of fostering associations for training agents in the production chain.

As regards to blood, organs and tissues, is highlighted the creation and reformulation of the legal bases for cell and germ layers for assisted human reproduction banks, eye tissues, transportation of organs for transplants, histocompatibility and immunogenetics laboratories, operation of hemotherapy and laboratories for processing haematopoietic progenitor cells, as well as embryo banks.

Within the regularisation of personal hygiene products, cosmetics and perfumes, Anvisa grants low risk permission – 1st degree – and registration for 2nd degree products (sunscreens, hair straighteners, etc.). Other than elaborating technical regulations, cosmetovigilance (adverse events) has been instituted, as well as the enhancement of control, with reference to European, FDA and CIR (Cosmetic Ingredient Review) directives. So as to harmonization, it has been reached 100% on this issue. In the future, it's expected to extend surveillance of the products in the market, as well as simplifying the registry of 2nd degree products. A similar scenario can be seen for disinfectant products.

Anvisa has a specific regulation for the control of tobacco products, as rules have been established for its commercialization, inspection and advertising control. This and other strategies have permitted a 33% reduction in the number of smokers in 1990 and 17% in 2008.

In regards to products for health, there are specific proceedings depending on the risk category of each product. For registry, companies must present best manufacturing practices from the facilities developing these products.

So as to pesticides, it has been managed to prohibit, reclassify or recommend the withdrawal of the market of products that have been through toxicological reclassification. There is a joint work with the Ministries of Agriculture and Environment for the evaluation and registry of such products.

The number of inspections of medicines and products for health has been increasing on a yearly basis in the past few years, as well as the inspection of pharmaceutical facilities, cosmetics and disinfectants.

The control of ports, airports and frontiers, through the inspection and authorization of import and export of products that are subject to sanitary surveillance is carried out at a national level. International vaccination certificates are issued for passengers; aircrafts, land transport means, vessels, port and airport areas are inspected, as well as service providers in terms of sanitary surveillance. Other inspection activities are decentralized in states and municipalities.

Anvisa has established best regulatory practices under the guidelines of strengthening its institutional capacity for managing regulation, enhancing the coordination, quality and effectiveness of rules, as well as strengthening this process's transparency and social control. It has a number of strategies to this purpose: guidelines of best regulatory practices, regulatory agenda, analysis of regulatory impact, revision and consolidation of health legislation, training and qualification for regulatory practices, and strengthening of the social participation in regulatory processes.

The joint work between the Health Ministry and Anvisa has resulted in the improvement of the regulations on advertising for food, medicines and tobacco. Additionally, projects to foster education and information in health have been developed.

Anvisa has a health risk communication system through the publishing of manuals, guides, alerts, newsletters, technical notes, letters to health professionals and issuing in the official gazette.

An unprecedented database was launched with information of prices of products commercialized in Brazil that allows for comparison with products from abroad.

The Chambers for the Regulation of the Medicine Market was created to control the price of drugs. The analysis of economic information is required for the registry of medicines. The examination of the price of new drugs is based on concepts of health technology availability and pharmaco-economics. It has a database with around 20,000 medicines presentations, which permits the monitoring, analysis and diagnose of the pharmaceutical market. There is a policy for the annual readjustment of drug prices. A database with information of costs and prices of medical equipment is currently being created.

For the incorporation of new technologies, Anvisa evaluates requests of extraordinary import licences for unregistered medicines in Brazil in order to supply specific needs where there is no therapeutic replacement in the national market. The priority is set for the registry request of those products considered strategic for supplying the programmes of the Ministry of Health.

The coordination and international joint actions are aimed at institutional strengthening, exchange of knowledge and experiences, formation of networks with health authority of other countries and strengthening of regulatory authorities in Latin America.

So as to laboratorial support, there are the National Network of Laboratories of public health surveillance formed by main laboratories of public health (LACEN) and the National Institute of Health Quality Control (INCQS). Anvisa coordinates the actions carried out by the laboratories that analyse products of sanitary interest, guaranteeing trustworthy results for the population. In addition to that, there is the Brazilian network of analytical laboratories in health (REBLAS), formed by regulated laboratories. The analytical pre-market tests can be carried out by public or private laboratories, which are authorized through different mechanisms of verification of compliance with best laboratorial practices. Official laboratories carry out the analytical post-market tests.

The Ministry of Health's Crisis Unit and the Centre of Information and Response on Health Surveillance (CIEVS) elaborate plans for problem resolution in emergency contexts. The creation of a quick Response Unit is currently being considered in order to provide a systematic and articulated response among the different organizational units in the event of outbreaks related to the investigation of product and services under the sanitary surveillance regimen.

The strategic agenda includes the interaction of the Federal Government efforts within the programme "Brazil without poverty and Greater Brazil", the interaction with the strategic agenda of the Health Ministry, focusing on strategic governance and on the decentralization and strategic coordination of the National System of Sanitary Surveillance (SNVS).

Among the challenges and perspectives, it may be highlighted the re-evaluation and prioritisation of risk management, the simplification of processes and the modernization of management, strategic planning, strengthening of social participation in the assessment and regulation process, surveillance activities as means to promote economic development and innovation, development of a consolidated strategy for risk communication and strategic association for resource optimization; as well as strengthening of sanitary surveillance capacity and inserting the activities developed by Anvisa into the regional and global health context.

## CHILE

### **Presentation of Dr Paola Pidal Méndez, Chief of the Reference National Biomedical Department**

Sanitary surveillance is substantiated by legal norms since the Sanitary Code, specific rules for the subject, technical rules, resolutions, notes and guidelines. It is a State's responsibility to protect individual and collective health through the collection of data, analysis and dissemination of information, and by carrying out actions. The work is performed across ministries, with the participation of the Ministry of Health (Public Health Institute), the Regional Secretaries (Seremis), the Health Superintendence and the health services, the Ministry of Agriculture (the Agricultural and Livestock Service), the Ministry of Finance (National Customs Service), the Ministry of Economy and Promotion (National Fishing Service), the Ministry of Labour (Board of Labour) and the Ministry of the Interior (National Emergency Office).

The Seremis is made up by 15 Regional Ministerial Health Secretaries and is the health authority of medicines and health facilities of the public and private network since 2005 (Health Reforms). It is also the Health Authority for food. It grants sanitary authorization and performs inspection and epidemiological investigation.

The Public Health Institute (ISP) is unique in the country and features the National Agency of Medicines (Anamed), which carries out the surveillance of medicines and medical equipment. It has clinic laboratories and a blood bank for the laboratory epidemiological surveillance.

There are 29 health services spread throughout the 15 regions, which assists and guides healthcare facilities of the public health network.

Its actions span pharmacy, pharmaceutical products, tobacco, health supporting laboratories, blood banks, medical equipment, cosmetics, pesticides, advertising, authorization for the import of products subject to sanitary surveillance and customs control. Pre-market surveillance requests the manufacturer the presentation of stability researches of pharmaceutical products, as well as analytical control for imported products. In the post-market, shelving control is performed in ISP laboratories, which are validated by WHO, based on claims over the quality of products subject to sanitary surveillance. Rules of best manufacturing practices are also verified in the laboratories.

In Chile, sanitary surveillance is multisectoral. On the other hand, due to the extension and diversity of its territory, the elaboration of local strategies is necessary: Seremis and Regional Customs.

## COLOMBIA

### **Presentation of Dr Rodrigo Moreira, Advisor of the Minister of Social Protection**

The institutional structure in sanitary surveillance is formed by the Ministry of Social Protection (MPS), a governing body for health policies and regulation; the National Health Institute (INS), a governing body for epidemiologic surveillance; the National Institute of Medicines and Food Surveillance (Invima), health authority in charge of the surveillance and risk control for the use of food, medicines and health inputs; the Institute of Technological Evaluation in Health (IETS), which is responsible for the evaluation of technologies on proceedings, medicines and items of the Benefits Plan, of medical technologies, proceedings and healthcare; and the ETS, which is in charge of the inspection, surveillance and control of the distribution chain, commercialization of medicines and inputs, and actions of epidemiological surveillance.

Decree 1,290 of 1994 created Invima and established its basic structure, whereas Decree 211 of 2004 defined its current functional structure. It has four sub-branches: health registry, food and alcoholic beverages, medicines and biological products, health products and various products. Its functions comprehend granting and/or renewing health registries, authorize product advertising, pharmaceutical and pharmacologic evaluation of medicines, issue health registry and permission for the manufacturing and sales of food elaborated by micro-entrepreneurs, issue health inspection certificates and approval for imports, issue compulsory health certificates for cosmetic products, grant permission for the commercialization of biomedical equipment, carry out visits to facilities to verify best manufacturing practices, production capacity, storage and/or conditioning capacity, issue sanitary concepts, health authorization for processing plants, official inspection of processing plants, and authorization for the import of meat and meat products.

In 1995 its labour force was made up of 123 employees and, nowadays, its staff has 481 members.

Among its strengths, we can highlight the effective legal framework that consults, adapts and adopts international recommendations, the certification of Invima as Reference National Regulatory Authority, the model centralized in the rulings and decentralized in the execution, and the increasing use of new information technologies.

So as to weaknesses, it may be noted the normative “inflation”; overlapping; duplications and empty spaces; imbalance of tools acting over different groups of products subject to surveillance; the decentralization of the execution, which leads to different degrees of efficiency according to local capacities; rising workload for the human resources and inefficient information systems.

## ECUADOR

### **Presentation fo Dr Linley Lara, Technician of the Pharmacotherapeutic System of the National Board of Sanitary Surveillance and Control**

Since the creation of the Ministry of Public Health (MSP) (1966) and in accordance with the Health Code (1977), which was replaced in 2006 by the Health Organic Law, sanitary surveillance has been regulated by the Board of Health Control. According to the new Ministry of Public Health's organic law of organizational management (November 2011), the National Board of Sanitary Surveillance and Control is in charge of designing surveillance and control for the application of technical rules, policies and regulations of the corresponding entities, so as to improve quality, safety and efficiency of products subject to health registry or compulsory health notification. It performs on the hygienic-sanitary conditions of facilities and other processes of its competence as well. The National Institute of Hygiene and Tropical Medicine "Dr Leopoldo Izquieta Pérez (INHMT"LIP") grants health registries and carries out sanitary control, among other activities.

INHMT"LIP" was created in 1937 with a different name through a decree that established the obligation of obtaining a "patent" in order to elaborate and sell chemical and pharmaceutical products in the country. Ever since, a number of transformations have taken place and there is a Decree for the partition of INHMT"LIP" and the creation of the National Agency of Regulation, Control and Sanitary Surveillance (ARCSA), which will concentrate all actions of registry, post-registry control, as well as the issuance of operating permissions, best manufacturing practices, advertising control, pharmacovigilance, and other formalities of sanitary surveillance and control.

Until this agency starts its operations, the work scheme carried out by the main level and the 24 Provincial Health Managements (one for each province) and INHM"LIP" is maintained. INHMT"LIP" has been transformed into the National Institute of Public Health and Research (INSPI) (1 headquarters, 2 regional branches and 19 laboratories). Its fields of action include cosmetics and hygiene products, pesticides of agro-industrial use (along with the Ministries of Agriculture and Environment), medicines, natural products processed for medical use, homeopathic products, medical equipment, grants for the advertising of non-prescription products, control over tobacco and alcoholic beverages, and issuance of certificates of good manufacturing practices, among others.

The workforce includes 145 professionals and 48 administrative employees working in the INH and 700 employees working in the MSP.

The existence of a constitutional and regulatory framework for sanitary surveillance and control is identified as strength. In this moment, a reform process of State modernization is being carried out, which will allow the structuring of the agency as well as the creation of a single window procedure (online procedures), the control in the medicines price establishment, emergency plans and alerts oriented by the National Connection Centre of the National Board of Epidemiological Surveillance.

It is necessary, therefore, to strengthen the training of professionals working in VISA, the control of incoming and outgoing products in ports, airports and frontier checkpoints, risk communication, incorporation of new technologies and laboratorial support.

## **PARAGUAY**

### **Presentation of Dr Pasionaria Ramos, General Director of the National Board of Sanitary Surveillance**

The Sanitary Code (Law 1,119/97) created the National Board of Sanitary Surveillance within the Ministry of Public Health and Welfare, and its objective is to ensure the efficacy, quality and safety of medicines; guarantee its rational use and facilitate its access for the population. It has autonomy and self-sufficiency. Its tasks are to regulate the manufacturing, elaboration, fractioning, quality control, distribution, prescription, dispensation, commercialization, representation, import, export, storage, rational use, price regimen, information, advertising, as well as evaluation, authorization and registry of products subject to Sanitary Surveillance; prevent and promote health of the people, specially of the consumer, through quality control. It proceeds through regular work or after complaints.

Its action field comprehends medicines of human use, controlled drugs to the pharmaceutical industry, chemical products for the pharmaceutical and non-pharmaceutical industry, reagents and any other product of use or application in human medicine, cosmetics, household products (Risk I and II), tobacco, phytopharmaceuticals, medical equipment, pharmaceutical patents – donations (campaigns).

It has six departments: evaluation, authorization and sanitary registry, IT, control, quality control, inspection and surveillance, pharmacy and pharmacovigilance, and the department of management and finances. Its workforce includes 90 employees in the main level and 20 in the sanitary regions.

The pre-market control is carried out primarily for national and imported products, and the post-market control is performed in retailers and by complaints. There are four laboratories for this purpose, which generates conflicts of interest.

The emergency plan is managed from the epidemiological surveillance.

Strategic challenges include: strengthening of stewardship as health authority, full implementation of self-sufficiency and autonomy, implementation of best regulatory/governance practices, increasing the capacity to comply and enforce the legislation, implementation of a system of quality management.

There are challenges arising from new issues: biotechnology, clinical studies, bioavailability of medicines, the Paraguayan and the MERCOSUR Pharmacopeia, the use of risk management and epidemiology as tools of surveillance.

Among its strengths, we can highlight: self-sufficiency and autonomy, commitment of the health authority, decentralization through the sanitary regions, pre-evaluation as sanitary authority by PAHO, strategic plan, personnel training, good relationship with other sanitary authorities (Anmat, Anvisa), implementation of horizontal cooperation projects (ABC/Brazil, FOAR/Argentina), pilot experiences in implementation (generics plan, medicinal plants), exponential growth of the pharmaceutical market (exports) (opportunity).

As weaknesses we can point out the human resources (quantity, quality, stability), physical infrastructure (lack of an official laboratory), lack actual presence in customs control, insufficient pharmaceutical personnel for the market.

## PERU

### **Presentation of Dr Percy Ocampo Rujel, Executive Director of Sanitary Surveillance and Control**

Peru has a clear structure from the organizational and functional point of view, which is based in laws, rules, and lower level norms that are permanently implemented. We can point out the General Board of Medicines, Inputs and Drugs (Digimid), within the Health Ministry, where the Board of Sanitary Surveillance and Control is included. This board has four teams for sanitary surveillance and control of products, pharmaceutical facilities, quality of the advertising, and control and eradication of the illegal commerce.

There are policies, laws, regulations and specific tools for the fields of action of sanitary surveillance, which guide the development of the activities. There is the control and surveillance of food, pesticides and agriculture chemical products, medicines, pharmaceutical products, medical equipment and sanitary products. The board issues sanitary authorizations for operations, certification of Best Manufacturing Practices and Best Agricultural Practices, carries out research of products and regulatory inspections, documental and operations verification, and control of outgoing and incoming products in frontier checkpoints. The board has identified the main trafficking routs and fights the illegal commerce of medicines.

There is probably a lack of workforce to develop all the control and surveillance activities comprehended in the new regulations. For the professionals in the activity, there are training plans that are developed with own resources or contributions from international institutions. The workforce has 156 employees working in the Digimid and approximately 100 pharmaceutical professionals working in the 34 DIREAS all over Peru, which comes to around 256 employees.

So as to medicines, Digimid keeps communication platforms from the population and towards the population, and administered ones, which inform on control and surveillance activities. The coordination international activities are concentrated in the Health Ministry. Digimid doesn't have an office of international coordination.

One of the strengths of Peru is the international certification of the National Centre of Quality Control; however, it is necessary to expand the installed capacity due to quality control needs of all the first batches of products to be commercialized in the market and of the future research plans. There is a decentralized network of laboratories for quality control. It is necessary to expand the technological development towards technologies for the quality control of medical equipment and sanitary products.

Finally, Digimid doesn't manage emergency plans, as those are centralized in the Health Ministry.

## **SURINAME**

### **Presentation of Dr Miriam Naarendorp, Coordinator of Pharmaceutical Policy / Chief of Pharmaceutical Inspection**

Among the Health Ministry's activities and some other institutions, there are those related to medicines, food, blood, tobacco and pesticides. The medical products, cosmetics and hygienic products are not regulated. There is an available legislation on medicines, foods, pesticides and, partially, on medical products. Also, there is laboratorial support for all products, with the exception of medical products and tobacco.

Focusing on that, regulations are supported by the available legislation.

Its workforce is made up of four regulators for pharmacy, foods, environment and laboratory.

Some negative aspects: obsolete and confusing legislation on medicines (1876-1980), weak coordination, implementation and communication of the national policy on medicines, serious problems in the availability of technical information, work conditions must be improved, budget limitations, poor market surveillance,

illegal imports, unregistered essential medicines, the registry committee must enhance its work of registry and regulation, great quantity of little importers, small barriers for business conduction (Ministry of Commerce) and free trade agreements.

Some positive aspects: National Medicines Policy available, existence of some key functions (registry, laboratory, inspection) and other under way (pharmacovigilance), close connection between essential medicines and financing (economic regulations, use of generics, rational use of medicines), recent investment of pharmaceutical lab, firmly established public health staff, international and regional cooperation.

## URUGUAY

### **Presentation of Dr Catherine Vanina Ausqui Arbelo, Technical Evaluator Physician of the Public Health Ministry**

Within the Public Health Ministry, there is the General Board of Health (Digesa) dedicated to Sanitary Surveillance activities, which is divided into the Epidemiological Division, the Environmental and Occupational Health Division, the Sanitary Evaluation Division, the Sanitary Rules Division, the Inspection Division and the Unit of Territorial Decentralization.

The municipal Intendancies, the Ministry of Territorial Planning and Environment, the Ministry of Livestock, Agriculture and Fishing, and the Technological Laboratory of Uruguay are organisms that are also involved.

The products that are involved in Sanitary Surveillance activities are medicines, medical equipment, diagnosis reagents, therapeutic devices, food, cosmetics, household products, blood and blood products, tobacco, and health services. There is also the frontier control.

The workforce has 48 employees in the Health Evaluation Division.

The communication of sanitary risks and pharmacovigilance is carried out through the webpage and the press.

The laboratorial support is performed through the Commission for the Quality Control of Food (CCCM) that analyses and samples the products to be released in the market.

Related to emergency plans, in 2009 the National Emergency Plan was established with actions aimed at preventing risks related to predictable and unpredictable, periodic or sporadic natural or human disasters; to the mitigation and care to phenomena that may come up; and to immediate rehabilitation and recovering tasks that may be necessary.

## VENEZUELA

### **Presentation of Dr Ana Lucía Mosqueda Palacios, Autonomous Service of Sanitary Control**

In order to perform Sanitary Surveillance activities, there are: the Autonomous Service of Sanitary Control (SACS), which is inside the structure of the Ministry of the People's Power to Health with regulatory functions; the National Hygiene Institute "Rafael Rangel" (INHRR), for technical-scientific support; the Pharmaceutical Products Review Board; and the Ministry of the People's Power to Health as governing body. Among its functions, we may point out compliance with the public health policies for the registry, surveillance and control of products of human use and consumption, and pharmaceutical facilities at a national level; it must enforce sanitary rules, laws and regulations that govern the national system of sanitary control.

The SACS is made up of three fields: equipment, materials, facilities and health professionals; drugs, medicines and cosmetics; and food.

The INHRR includes the following areas: food, pharmaceutical specialties and medical materials, biological products and medical materials of biological origin, natural products and cosmetics.

The Pharmaceutical Products Review Board advises the national regulatory authority. It is an autonomous collegiate body integrated by professionals of proven experience who are not associated with the pharmaceutical industry.

The Sanitary Surveillance activities performed are: inspections of Best Manufacturing Practices and Best Dispensing Practices (SACS, INHRR), grant of clinical studies (JRPF, INHRR), sanitary registry (INHRR, SACS), batch liberation (INHRR), post-commercialization surveillance (SACS, INHRR, CENAVIF), programmed laboratory control (INHRR).

The workforce includes 566 SACS employees, 628 INHRR employees and 6 members of the Pharmaceutical Products Review Board.

There is a process for the communication and risk promotion towards the community, and national and international authorities through information media, newsletters and the alert network for false and counterfeit medicines.

Among our strengths it may be highlighted: the sanitary surveillance structure - the legal framework -, the training of sanitary surveillance professionals, the risk communication and the emergency plan.

Among our weaknesses it may be pointed out: the structuring of the agency, the regulation of products subject to sanitary surveillance, control of income or outgoing products or persons and of frontier checkpoints, ports and airports, the incorporation of new technologies, price control and laboratorial support.

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## NOTES

- I - In Argentina and Venezuela, for example, the popular reaction to Menem's and Pérez's neoliberal measures, respectively, were radically the opposite, which can be clearly seen as they backed the re-election of the former and led the latter to political judgement.
- II - Finding of the authors.
- III - E-mails have been sent to all South American countries with the request for revision and rectification of the information presented in this chapter. The present information is a summary created out of the author's independent understanding.
- IV - Administrative Decision 22/03, published in the Official Report of the Argentinian Republic of March 17<sup>th</sup> 2003.
- V - Law 8080 of 1990 on the creation of the Unified Health System – SUS.
- VI - Law-ranking Decree (DFL) 725/1967, ultimately modified in September 2011. Available at <<http://www.leychile.cl/Navegar?idNorma=5595>>
- VII - Database, National Board of Sanitary Surveillance and Control.



### **III. The role of Health Surveillance on the quest for safety, access and innovation boosting in medicines, medical products and food**

*Roberto Lede  
Teresita Traverso  
Julieta Gandini*

**T**hree Health Surveillance areas of undisputed competence, medicines, food and medical products, share basic premises making up for the activity's fundamental purpose. They could be described as aimed towards assuring the peoples' access and consumption of quality, safe and effective products for the protection or reestablishment of their health. In order to fulfil the tasked proposed, it is important to highlight the particularities surveillance authorities should be required in order to perform its role with effectiveness.

Colombia's regulatory authority, National Institute for Control of Medicines and Food (Invima), express in a official document<sup>1</sup> concepts that, without a shadow of doubt, are appropriate in order to make an introduction to the subject. The document highlights the critical part medicines hold on health policies because they represent a fundamental supply for the total surveillance assistance of the population. Medicines are the main actual therapeutic tool, acting as a determining factor in the quest for equal opportunities through political policies. Thus, the importance of assuring the quality, efficacy and safety of the medicines consumed within the country. Therefore, it is necessary to strive for the improvement of actions aimed towards control and surveillance from the health authorities guarantying the population the medicine's circulating in the country are in accordance with quality requirements. The strengthening of the regulatory organisms is paramount, as well so as to restrict or eliminate the access of fake, unmixed or expired products or even smuggled goods into the medicine chain.

When we talk about medicines, there are no degrees for quality; there are no medicines "a little" better than others: only good medicines (those that comply with all standards of quality of the drug's directory) and bad medicines (those products that are not in compliance with at least one of those standards). The effect

hoped for by the patient and by the health professional must necessarily happen; otherwise the medicine mustn't be on the market. The firm action the surveillance authority must be based on the compliance with the law and on ethical principles agreed between all the agents of the medicine chain.

Neither it is considered enough for the medicine to be produced with quality. It is mandatory that the quality be maintained from the production to its final consumer, the people, as people are the State's main concern. In order to strengthen the regulatory authority, in accordance with international guidelines, it is imperative the political and public involvement, the cooperation of safety organisms and the ongoing training and instruction of its staff.

The control and systematic compliance with best practices in manufacturing and perfecting of the sanitary registration are essential measures and of critical importance to assuring the medicine's quality. Additionally, it is important to work on best practices regarding the transportation, storage, distribution, dispensation, surveillance and control.

Paraguay's surveillance authority<sup>2</sup> affirms that a program of Health Surveillance is aimed towards assuring the population's consumption of quality of products, safety and efficacy, establishing actions of control of Sanitary Surveillance and promoting the rational use of drugs.

As regards to the Mercosur policies<sup>3</sup> on medicines, it is aimed towards supporting the states improvement of action, mainly when it comes to its basic objectives, which can be described as follows: extend the access to medicines to the population considering the necessities of different social groups; promote the habits of rational use of drugs; create an environment favourable to the development and research of medicines; guarantee the safety, efficacy and quality of the medicines on the region.

It can be said that there is no discussion as regards to the pertinence of the relevancy of the availability of efficacious and safe medicines for the population, as there is no such discussion regarding the necessity of offering human and normative resources to facilitate the achievement of this objective. It is also inherent of such regulatory organisms the surveillance over the real therapeutic contributions offered by the available products. On the bibliography, there are studies showing that "novelties" often don't represent any significant progress to the therapeutic arsenal. For instance, studies carried out in France estimate that 70% of the new products don't represent a real therapeutic advantage<sup>4</sup>. In a similar study by the Food and Drug Administration (FDA), that estimate reached 84%<sup>5</sup>.

Therefore, we come to one of the fundamental themes, which relate to the discussion over what we understand for "control", and for the key role of the regulatory agencies. From the 70's to today, the scientific community was pushed towards being responsible of the regulations for public health risks associated to

science and technology innovations. Regulations as a process is long-established and, in fact, translate into the development of rules for an activity, process and/or features of a product, which leads to establishing distinctions in the interpretation of such concepts within real regulating processes. It could be designated as a “static normative picture”.

When regulation involves inspection and control, it becomes an even more complex process that implicates decision-making on a technical knowledge basis. This knowledge changes overtime due to the development of new knowledge, which may generate disparities in the meanings of regulation and application criteria and may be interpreted and applied in different ways by the diversity of social actors involved in regulation.

As opposed to the vision previously described, which we call “the frozen image”, there is the “dynamic or adaptable regulations” vision.

With extended social awareness of the new technological risks, Science, which is the only way we have so as to identify them, has transformed into regulatory science, an activity that is guided through different agendas from the academic sciences, ruled by maximum rigidity as regards to predictions and findings. It is through science that public health is protected and promoted. Scientific innovations create tremendous opportunities to improve the way new products are developed and evaluated.

This vision, which entails that the decision-making is based on scientific-technical knowledge with risk/benefit evaluation, generates a context in which the regulatory concepts are directly related to the information originated from technical and scientific knowledge, allowing for the effectiveness of the regulatory processes, since they work as implicit and explicit guidelines for decision-making. Its appearance, which is partially due to the fact new hazards are not directly noticeable by the citizen, has meant that, in one hand, scientific activity penetrated in the social sphere and, on the other hand, that the state became more needed to protect the citizens. The articulation of those who understand what is convenient and have the information and those who know what is possible must be sought.

The regulatory science<sup>6</sup> is a fundamental link, a bridge between avant-garde finding and the real world; the way in which technological risks change the criteria of the scientific activity for the benefit of public health and the safety of the surroundings. It is, thus, the result of decisions adopted within the context of technological innovations’ policies, in order to guarantee that this knowledge is relevant and effective.

Regulatory science<sup>6</sup> is a practice that should guarantee safety, quality, efficacy and effectiveness of products and technology for the population. Regulatory organisms, like sanitary authorities, whose responsibilities encompass decision-making over the authorization of certain products, should include, for example, the assessment of the impact of new technologies and toxicity of the substances.

Regulatory sciences sustain several characteristics that differentiate it from what can be denominated as “standard scientific practices”:

1. The social relevance of its conclusions, since they directly affect the health and safety of the population.
2. The high rank of empiric determinations. Frequently, when it comes to regulatory sciences, the data is not entirely conclusive. Consequently, its interpretation can be controversial.
3. The importance of timing. The regulatory authorities agents should produce fast and substantial data as a fundamental supply for decision-making. They must be based in the best possible evidence, which, however, is frequently incomplete or contradictory. In other words, it is not possible to wait for all the data and its details to be generated.

Scientists producing data for regulatory decision-making face the necessity of taking fast decisions based on incomplete or contradictory databases, regarding controversial subjects and, moreover, under the scrutiny of a vast variety of affected social actors (final consumers, politicians, companies, nongovernmental organizations, etc.).

If the selection of the research’s methodology (in some cases including the results) depends on previously choosing principles and objectives, it means that the justification of the methodologies of the research, its results and decisions within the context of the regulatory science makes previous and explicit deliberation necessary for those principles, including the practical ones.

Science produced for public policies purposes (regulations) or the result of them (innovations) has to resort to the practical values of knowledge generation in order to be relevant and effective, fulfil its objectives (scientific-technological regulation for the protection of health and environment to the strive for innovation, respectively). A knowledge produced with no concrete link to the objectives of its eventual implementation would not be relevant to public policies.

Some relevant principles and concepts should be taken into consideration when we talk about regulatory science, such as:

1. Uncertainty principle
2. Precautionary principle
3. Non-standard analytical methodology
4. The weight of the proof

Each of them is oriented to conform necessary information for action.

## UNCERTAINTY PRINCIPLE

On the past years, the management of the scientific uncertainty has been based on a premise in which regulatory science, ruling over the proceedings, methodologies and principles of the scientific-academic field had to be adapted to the objective of facilitating regulatory decision-making.

Uncertainty is not necessarily an accident or exception on the scientific practice that exceeds itself with new knowledge. It is not restricted to knowing forecasted risks through the process of evaluation, but also to confessing uncertainties and scientific lack of awareness found during the analysis.

One example of this asseveration is the relationship between chemical structures, biological activity and new diagnosis technologies and/or treatment.

However, uncertainty can also be artificially generated, a process known as “fabricated uncertainty”. An artificial raise in the level of difficulty uncertainty, during the regulatory practice decision-making is based in a non standard methodology.

## PRECAUTIONARY PRINCIPLE

The precautionary principle indicates an alternative manner of understanding regulatory activity. This should be considered within a structured risk analysis frame. There are three main elements: risk evaluation (scientific phase), risk assessment (political phase) and risk communication (social phase), successively.

In order to use the precautionary principle in risk assessment, the following conditions must be met: scientists must have identified the dangerous effects of a phenomenon, product or process and the scientific evaluation couldn't determine the risk with enough certainty; the implementation of an approach based on the precautionary principle should come from a scientific evaluation and, if possible, during each phase of identification, estimation and value of the level of correspondent scientific uncertainty.

Precaution relates to a manner of interpreting the problems with its merits and to conceive the responsibility in the presence of its impacts, in such a way that the normative sense is incorporated in order to interpret whether knowledge is acceptable.

It is indispensable to take into consideration this principle as a guide to the development of regulations and policies related to the possible negative impacts of the technological implementation over health and its surroundings.

Those interpreting uncertainty as the lack of timely scientific knowledge, consider the precautionary principle as a guideline to design public policies when three conditions are met:

1. when there isn't reliable knowledge about the risks;

2. when there is the suspicion that harm to the public health and/or to its surroundings could be produced; and
3. when those damages are significant.

## **NON-STANDARD ANALYTICAL METHODOLOGY**

The methodology to be selected must be fast and accessible, and should provide relatively trustworthy information so as to facilitate the regulatory decision making process in a comparatively short amount of time.

## **WEIGHT OF PROOF**

Three main types of weight of proof can be distinguished:

1. qualitative
2. classificatory (establishing hierarchy amongst the different characteristics of the case of study)
3. quantitative

The effectiveness and precision of the weight of proof depend on:

1. the quality of the data
2. the quality of the studies' design
3. the skills of the researchers
4. the severity of the possible damage
5. the relationship between the objectives and the data

The standpoint of decision-making according to the weight of proof takes into consideration the accumulative weight of information coming from numerous sources addressing the subject of harm or the probability of harm to be caused to the population.

The training of regulatory agencies and surveillance officers' relationship to the aspects cited previously allows its application to the inherent tasks of health products' sanitary surveillance.

## **FOOD SURVEILLANCE**

The domestic systems of food control are generally organized on a complex mechanism basis comprised by different actors belonging as much as from the health area as the agricultural and environment sectors.

In this context, food surveillance can be defined as a group of activities of reception, search, registering and research carried out by the authorities in place

aimed towards getting to know better the health-hygiene condition of food products, materials in direct contact with them, and food establishments. The objective is to identify potential dangers, evaluate probabilities and gravity of eventual harms to the health, and develop strategies for the management of risks. Therefore, the policy for food innocuousness should be based on risk analysis.

The surveillance system, consolidated through the promotion of mutual cooperation actions and fast information exchange between members of the system, should work, in the short term, to:

- Detect potential dangers present in food products; question the causes of its presence, evaluate risks managing them immediately, through the seizure of the product from the market, correct the malpractices in every moment of the chain of production.
- Investigate cases and outbreaks of diseases allegedly transmitted by food products with the objective of identifying its food origin and, in this particular case, identify the group of affected people, their geographic distribution, the type of food involved, the possible carriers, the responsible etiologic agents, the transmission manner and factors regarding the environment favoring its occurrence in order to avoid new cases.
- Reveal incidents related to food products nationally and internationally permitting and anticipating actions aimed at the reduction of risks associated to them in a local level.

In a long term, it is expected:

- To identify tendencies of food contamination
- Recognize emerging pathogens
- Provide tools for the elaboration of intervention strategies aimed at preventing and controlling diseases transmitted by food products (ETA); and evaluating the level of effectiveness of food programs and regulations implemented to this purpose.

To achieve that, it should be capable of incorporating to the system the information coming in from different sources:

## **SURVEILLANCE PROGRAMS**

1. **Surveillance program for contaminants and nutrients:** based on the sampling and lab analysis of food products in the national markets, being imported or domestic, industrialized or not, which can represent a health hazard to its consumers based on its components, consumption levels or target population.

The goal is to acquire knowledge over the products' hygienic quality, nutrition and label consistency with the purpose of evaluating the impact on health, manage potential risks and prevent the occurrence of ETA. Due to the amplitude of the sampling, it should rely on a chain of official food surveillance laboratories covering all extension of the national territory.

2. **Imported food products monitoring:** based on the sampling and lab analysis of foods, prior to entry into the country, with a regularity relating to its level of health risk and with the objective of assuring its adjustment to the national rules in place.
3. **Community information:** information regarding facts that might constitute a violation or a health hazard to the public health coming through community complaints is an important source of information for the surveillance system and should be evaluated and investigated. To that end, criteria for acceptance, rejection or derivation must be put in place in order to avoid the juxtaposition of actions amongst the different actors of the food surveillance system.
4. **Epidemiologic surveillance of foodborne diseases:** despite the efforts of sanitary surveillance to prevent the occurrence of foodborne diseases, on the event of an outbreak it becomes an object for investigation. The main source of information is usually notifications of medical outbreaks coming from primary healthcare facilities, although cases reported by final consumers or costumer's complaints shouldn't be unattended.
5. **International Information:** the last decade's markets globalization has widened the international supply of food, but also obligated the surveillance systems to extend its coverage to the origins of food related incidents. Different national agencies or international networks like Infosan<sup>7</sup> or Empres<sup>8</sup> are considered good tools for the surveillance of incidents of international relevancy, which might have an impact on the domestic situation.

People are usually unaware of the complexity surrounding food surveillance. The enormous quantity of products and producers to monitor along with the preparation and massive consumption of goods demands maximum effort from surveillance authorities intending to accomplish its surveillance objectives. On the other hand, the food market goes beyond a traditional idea of what it should be as it encompasses categories of products promoting care and tonic health properties, like the ones known as "health foods" and diet supplements over which there is still much discussion amongst the surveillance authorities as regards to the clear definition of its status and demands.

We cannot forget the possibilities of safety regarding intervention when it comes to processed foods, surveillance and controlling of new ingredients such as

harmful substances (for instance, salt and saturated fat) or favouring the adding of health protecting substances (such as iodine and iron) or defining maximum amounts of dangerous substances to a certain group of people (for instance gluten, for those suffering from celiac disease).

## POSITION OF OTHER REGULATING ORGANISMS IN THE REGION

In order to get to know the other agencies' opinions over this chapter's theme, they were invited to write their opinion in a brief document. A response came from Paraguay and Uruguay's authorities.

*The following text was sent out as a participation invitation:*

*We have the pleasure of reaching you regarding the book "Health Surveillance in South America", promoted by the South American Institute of Government in Health (Isags).*

*Argentina has been invited to collaborate during the elaboration of the part A of chapter II of the book, entitled: "The role of sanitary surveillance in the quest for safety, access and promotion of innovation of medicines, medical products and food."*

*It is of utmost importance for the fulfilment of this intent that you support us in this endeavour, as we believe the information given will enable to illustrate, in a beneficial and representative manner, Unasur's health systems.*

*We require you to answer the following question: How would you define and characterize the role of sanitary surveillance in your country?*

The answer received from the surveillance authorities of Paraguay reads as follows: "The role of the Sanitary Surveillance in Paraguay is imperative for its contribution to the maintenance of the population's health in a country where 90% of the national pharmaceutical production is destined to the domestic market, according to the document of the National Pharmaceutical Sector (MIC, ONUDI, CIFARMA; 2009).

*The main issues for National Bureau for Sanitary Surveillance (DNVS) are, for instance: the establishment of a National Medicine Policy cohesively structured and adequately executed, the reasonable use of medicine, the transition to the consumption of generic products and the fight against counterfeit are vital to Paraguay, which has been presenting a deficient quality of life if compared to other Latin American countries, especially with regards to the access to medicines.*

*The actual institutional strengthening of the DNVS, the coordinated participation of public and private institutions, and the harmonization of the regulations for the health sector within the Mercosur, are the bases conducting, in a directive manner, towards obtaining safe, efficacious and quality medication to the Paraguayan people”.*

Likewise, the authorities of the Oriental Republic of Uruguay responded commenting that, in the country, health products involved in Sanitary Surveillance include medicines, medical equipment, therapeutic devices and diagnostic reagents, food, cosmetics and household products.

The starting point are the companies' licensing and registering of products, in which each has specific legislation; some of the activities are: imports control, controlling and surveillance done in situ of the manufacturing companies, gastronomic establishments, pharmacies: as well as the labelling control and the products' publicity.

With regards to technological surveillance, experiences are interchanged within the Mercosur region in order to enrich and strengthen the work at a national level, improving the sanitary surveillance of the post commercialization of medical products.

They also highlighted that a National System of Pharmacosurveillance was in place and that, along with the Ministry for Public Health (MSP), several hubs of pharmacosurveillance across the country manage the actions with the Region and reports itself internationally according to the established protocols. Additionally, they underlined that, since 2007, the incorporation of technologies should be approved by the MSP, taking into consideration its scientific utility, usage necessity and geographic location validation.

## FINAL COMMENTS

The constant innovation of health products makes the task of Sanitary Surveillance increasingly transcendent and complex. This is why we insist in the necessity of developing and training regulating agents in regulatory science as a valid strategy to successfully face challenges. We understand that the region's agencies joint work and the provision of alternatives to specific and consensual professional training as one of the sound tactics to achieve it.

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## IV. Risks communication in Sanitary Surveillance

*Diana Ximena Correa Lizarazo  
Natalia Milena Acosta Amador*

*“Tell me and I forget, teach me and I may remember, involve me and I learn.”  
Benjamín Franklin*

**W**ith regards to a situation of public health's interest, the interventions and measures to be implemented by the governments require timings and resources stimulating the population to adopt safety behaviors and that they contribute to the understanding of surveillance measures turning into an important element to the sanitary surveillance's administration and a challenge to the Latin American governments requiring them to demonstrate results in the reduction of risks associated to the human health. As a consequence, it is necessary to understand concepts related to risk communication that will serve to Latin-American countries as means to implement strategies oriented to enhancing their sanitary surveillance systems.

In this context, this chapter treats communication as a discipline vastly seen from different knowledge fields focusing on the message and being capable of providing general frameworks for the construction of theories where the interaction and information flow are the cornerstone of the communication processes<sup>1</sup>. Although the scientific model is one of the most relevant models<sup>2</sup>, on the past decades health risk communication has grown in importance as part of a mounting effort of health authorities to present or mitigate the adverse consequences to the human health caused by several hazards, with the main goal of raising awareness of the community over these challenges through interactive, organized and conscious process amongst different sectors.

Meanwhile, sanitary surveillance or health surveillance refers to a group of actions under government authority dedicated to the welfare of the population. Their course of action or programs are aimed towards eliminating, reducing or preventing health hazards intervening in surveillance problems associated to environmental, epidemiological, social or healthcare which might constitute a risk

factor. In other words, its implementation is relevant to the sector, to systematic fact gathering, analyses and interpretation of data over health events, as well as the conditions to be used at the planning, implementation and evaluation of programs, including as basic elements of dissemination of information to all who need it. So, therefore, a more effective and dynamic prevention and control action in different levels is achieved<sup>3,4</sup>. Under the direction of international organisms of reference, which are to be mentioned later, governments have started to implement new and innovative concepts for the administration of sanitary surveillance when it comes to reporting risks associated to these activities.

In preparation, response and recovering of the population when facing an event, the communication of risks in sanitary surveillance is decisive<sup>5</sup>, and implicates an intersection among the stakeholders such as the government and its control agencies, scientific institutions, industry, consumers, scholars, amongst others, allowing that all of those expose to the relating threats, environment and safety to participate in the reduction and prevention of those risks in order to have a better understanding of those events<sup>6</sup>.

In this context, risk is understood as a probability to present a damage resulting from an individual or population exposure to a biological, chemical or physical danger, a situation that can surface due to toxicological, bioterrorism and pandemics emergencies, disease outbreaks, exposure to pesticides and other pollutants, environmental factors, amongst others<sup>7</sup>. In past decades, risks to human health have increased substantially due to the clear trend of a globalized economy, to changes in international trade, to new issues in food and technological production, to climate change and to expectations of sanitary and phytosanitary protection, as well as many others.

Health Risk Communication emerged in the United States during the 80's after several accidents around the world showed the necessity of an adequate management of crises<sup>8</sup>. Later, it gained momentum after the Chernobyl (Ukraine) incident, in 1986, when the authorities' lack of experience to deal with the situation and the difficulties for investigators to give the technical information over population's situation became evident. The next period was marked by a defensive attitude of surveillance powers and the mistrust of authorities<sup>9</sup>.

With this in mind, in 1989, the National Research Council (NCR) defined risk communication as a "*interactive process of exchange of information and opinion amongst individuals, groups, institutions, where multiple messages overlooking the nature of risk are present or expressing concern, opinions and reactions over the messages of risk and legal and institutional actions to the management of risks*"<sup>10</sup>. This approach is centered on the premise that scientific organizations must release technical information and gather data over the opinion and concern of experts, since, during a crisis event, the

approach is far more complex and often there is not enough time to consult with the community's representatives to determine their necessities and preoccupations<sup>11</sup>.

Following this tendency, the United Nation's Food and Agriculture Organization (FAO) and the World Health Organization (WHO) called for over 90 expert consultations in order to address the implementation of risk communication in the context of risk analysis, relating to food regulations and questions associated to innocuousness<sup>12</sup>. During this process, the role played by risk communication was studied as one of three components of risk analysis, coming to the conclusion that, along with evaluation and management, it is possible to take decisions with scientific considerations and along with the investigation of all options in order to look for the best solution when it comes to the peoples' safety in the event of incoming danger<sup>12</sup>.

In this regard, The Codex Alimentarius Commission (CCA) defines Risk Communication the as "*an interactive process of exchange of information and opinion along all procedures of risk analysis on risks, risk factors and risk perception, among people in charge of risk assessment, people in charge of risk managers, consumers, industry, scientific community and other stakeholders, including explanation for the results of risk assessment and decision related to risk management fundamentals*"<sup>13</sup>. To the CCA, the risks communication should go beyond the information release and should guarantee the making of decisions taking into consideration all the data and available opinions for the risk management to be effective and its implementation to be transparent and direct<sup>14</sup>.

Despite all the efforts to understand risks communication as a tool to risk management, in 1994 the world showed it wasn't ready when the first cases of transmissible spongiform encephalopathy (TSE) surfaced, known in cattle as Bovine spongiform encephalopathy (BSE) or "mad cow disease"<sup>15</sup>". In this case, when the disease emerged in 1985 in England, the political and scientific powers didn't have the adequate management of the information since they feared, amongst other aspects, the meat market clash on a global level<sup>16</sup>. A lot of mistakes were committed in this particular case; however, a lot of learning was also gained leading up to the process of modernization of the risk communication concept.

Therefore, to the Centers for Disease Control and Prevention, it is all about promoting the education of communicators so they are prepared to provide the necessary information for improving the conditions of decision-making when it comes to health and welfare. The Centers have developed a program of risk communication for crises and emergencies focusing on, primordially, in the Agency for Toxic Substances and Disease Registry<sup>17</sup>.

Consequently, and faced with different situations and public health problems that have had an impact on the world on the past decades, in the beginning of 2004, the

World Health Organization (WHO) started formulating norms for communication based on trust, early reports, transparency, community listening and planning as well as scientific trials which were submitted to practice essays to foment the fulfilment of the public health objective with minor inconveniences to the society<sup>18</sup>.

In summary, risks communication is no longer a mechanism to release information, and the gathered experience shows the necessity of strengthening the relationship between the risk evaluators, managers and all stakeholders, promoting knowledge and information exchange, generating trust in the decision adopted by the sanitary surveillance.

## FOCUS ON RISKS COMMUNICATION

The focus on risks communication may vary and its implementation depending on the receptor (to whom the message is directed), the message, management of conflicts and decision-making<sup>11</sup>. Although there are one-way channel models which are still in use, like the one developed by Claude Shannon in 1948, where the message travels from experts to non-experts, nowadays the most commonly used are the dual-channel models, product of academic works and researchers, which presents better results.

Nonetheless, the concept of risks communication can't be studied in separate manner without the understanding that perception is one of its fundamental elements. The risk perception is the ability to interpret a potential damage situation to the health or the life of one or another individual and the extrapolation to a future, in which the opinion can vary from a vague one to a firm conviction<sup>19</sup>. Social, cultural and economic factors determine the perception of individuals or of the community over health risks, since its known that those are interpreted and perceived very differently by the scientific community, health professionals, managers, politicians and the general public.

The identification of the public perception of a risk associated with a health event has been conclusive as a priority factor on the legislative agenda<sup>20</sup>.

From the 40's to the 80's different studies were carried out in order to identify the risk perception by the population over different types of dangers, amongst them natural and technological ones, showing that it varies according its magnitude, potentiality of assimilation over the danger, and that it is proportional to socio-demographic variables<sup>22,23,24</sup>.

Although historically two types of communication have been distinguished (the alert state and the calm state) this classification has been rethought, in such manner that the perception of danger/indignation vary accordingly<sup>5</sup>:

The previous relation present a variation of indignation perceived by the population when faced different dangers in a low, moderate or high level. Crisis

Chart 1 – Types of communication according to danger/indignation relationship

Types of Communication	Danger	Indignation
Public relations	High	Low
Relation of direct stakeholders	Moderate	Moderate
Indignation Management	Low	High
Crisis communication	High	High

Source: adapted from Sandman, 2003<sup>5</sup>

communication, when faced with a danger of the highest magnitude, presents the highest level of indignation, which means the population is more sensitive and needs to be informed on these cases<sup>5</sup>. In this aspect, and considering that sanitary situations are generally considered to be crisis, we must focus on the importance of risks communication when facing the events mentioned above.

Therefore, during the moment of defining actions adopted to communicate the interventions related to risk control, it is recommended to take into consideration that this communication could happen internally and externally, being the former the one among the members of risk analysis (evaluators, managers and communicators) and the latter, the exchange of information among such group, the external stakeholders and the general population<sup>25</sup>.

Consequently, according to the manner the government generates the dual-channel communication, being increasing or decreasing the perception level of a group or population, therefore, affecting the welfare of its citizens<sup>26</sup>. Despite of the low number of studies over the role of risk communication on public institutions, and more objectively, on government agencies, according to Garnett et al<sup>27</sup>, government communication involves the effective participation of a political stage of proceedings on operative terms.

In this regard, the concept of communication as a government role demands great importance when it comes to building consensus around public propositions, as well as disseminating information during a crisis and promoting trust on risk management agencies<sup>28</sup>. Additionally, the government can give out reliable information to the public over the risks and benefits of a certain activity, technology or emergency, etc. The challenge faced by the communication of risks and, above all, by the government agencies in all levels, is to serve the people giving out information related with different options<sup>29</sup>.

In this case, policies or actions formulated to develop communication risk strategies should favour decision-making based on complete, truthful and specific information, aiming primarily the community participation, equality and justice. During this process, the competencies of each institution should be delimited, as well as its surveillance role and responsive capacity.

## TAKING ADVANTAGE OF THE MASS MEDIA FOR RISK COMMUNICATION

Nowadays, the mass media has great influence on the population's perception over risks. On a globalized world, information of those risks can spread fast that's why it is so important for the South American governments to use information and communication's technologies, with a wider focus, in order to adopt better strategies in reaching a bigger share of the population with better outcomes.

With technological advances, mass communication have surpassed being unidirectional (where people are informed on one way manner) to become bidirectional, where people can participate with inputs, and share with others their interests. The mass media, for instance television, radio, internet, newspapers and its subsidiaries, like publicity, are an instrument to wire messages, inform, educate, teach and has become important to health authorities as a mechanism to communicate incidents and measures relevant to the population playing two major roles: providing the population with an interpretation of scientific information and of governmental policies and, at the same time, communicate the general public concerns to a greater number of people across the country.

Mass media are said to promote and strengthen behaviours when face with risks, so an inadequate approach to danger or risks could promote public doubts, alarms or chaos<sup>25</sup>. An important reminder is that risks communication is not a substitute for health education, which is abided by other principles and methods of long-term public concientization<sup>30</sup>.

Newspapers, magazines, radio, television in industrialized countries are the most influential source of day-to-day information over health risks, but less developed countries have shown great advances in this issue on the past years. Meanwhile, Internet mobile phones have become a challenge to the authorities since they have transformed the way we communicate. The globalization of information, its urgency and the capacity of the individual to turn into a message transmitter turn the traditional media no longer as efficient as means to reach out to the population, which nowadays require more information and critical thinking to form an opinion.

Organizations have more access to new information technologies related to communication, like email, cellular phones and social network, which can eventually have more influence or impact<sup>31</sup> when compared to the conventional media such as television and radio. Martinez<sup>31</sup> emphasizes these technologies should not represent a danger or difficulty. To the contrary, they represent ideal instruments to develop communication strategies contributing to showing a higher efficiency during crisis periods, eliminating distortions in the messages and creating a better environment for communication.

Although some models emphasize that messages and data transmitted through the mass media are more efficient on early stages, interpersonal communication and social network are extremely important on the post stages<sup>32</sup>. Researchers have investigated how social network can influence on the behaviour and attitudes of other people, concluding that, when facing a risk, a similar attitude and behaviour is adopted emulating others. The bigger the social bond and social interaction, the higher is the possibility of a cohesive reaction to risk. These social bonds can be also built through social network webpages such as, for instance, Facebook and MySpace<sup>11</sup>.

Due the importance of new communication and information technologies, it is suggested that Sanitary Surveillance entities in Latin America consider the following aspects in order to generate internal and inter-institutional mechanisms, which comprise:

- Defining relationships with the mass media and taking into consideration its determinants when it comes to facing a crisis.
- Generating connections and relationship with the media so, when faced with a crisis, the communication is not an improvised one.
- Contemplating social and human aspects showing transparency and interest.
- Giving out the maximum amount of information possible with the objective of achieving credibility with the general public and the media.

In addition to what was previously mentioned, the Pan-American Health Organization (PAHO) has formulated a seven-step strategy to an efficient communication with the mass communication media, which encompasses, amongst other things, assessing their necessity, limitations and capacities, establishing goals, plans and strategies, training of communicators, tailoring of messages, identifying the support for communication and activities with the media, releasing and evaluating messages and finally assessment of results<sup>33</sup>.

Governments should contribute for the open communication between the stakeholders before, during and after a sanitary surveillance event, since the public relies on mass media to obtain information. Additionally, it should consider that efficient messages are based on the understanding of the public concerns, regardless of the lack of scientific knowledge, for what is convenient to favour dual-channel dialogs where social, cultural, demographic determinants, amongst others might influence the perception of those messages<sup>34</sup>.

## STRATEGIES FOR RISKS COMMUNICATION

Trends in the last few years regarding health risk management have showed the necessity of laying out the strategies before a crisis appears, which means not managing the crisis but avoiding or minimizing it in a preventive manner<sup>31</sup>. Those strategies should consider the population's conditions, cultural, socioeconomic, and historic as well as those determinant aspects characterizing the nation.

Therefore, any efforts made on that direction, and specially coming from Latin American governments, should contemplate the public to whom the message is directed and channels providing the better chances of reaching a greater amount of people in risk, consequently, having more influence over them.

One of the pillars infusing more strength to strategies adopted will be that information given maintains the trust along all stakeholders in the face of the face of the management action proposed. As an axis, it is recommended to guide the communication actions towards the comprehension of the magnitude and seriousness of the risk, the urgency of the situation, the danger, probability of exposure to such danger, higher risk population, etc<sup>13</sup>.

According to the United Nations Food and Agriculture Organization (FAO), communication strategies should include, among other aspect, the following:

- a. Gather, analyse and exchange information over risk.
- b. Determine the knowledge and opinion of the people exposed to the risk.
- c. Interaction and intervention of all stakeholders, since communication allocates great importance to dialogue in order to give information enabling them to take the best possible decision. A well-informed population has better chances to react and to act.
- d. Using expert risk communication personnel, authorities and managers able to take decisions contributing to the maintenance of population's trust on its administration and on the recommendations adopted in order to assertively control the event.
- e. Ensure the communication is received and understood.
- f. Guarantee the openness and transparency throughout the entire process and that the delivered messages are clear and understandable.
- g. Determine the methods and means through which the information will be delivered.
- h. Explain the process applied to assess the risk

The previous recommendations are only a part of what could be some useful examples of sanitary surveillance, to which is recommended to study the options and context of every community before applying them.

That said, when it comes to Latin-American countries, two very interesting types of sanitary surveillance communication strategies are presented<sup>6</sup>, being:

- **Risk communication**, referring to the information exchanged and ideas over risks and actions to mitigate real and potential dangers that might generate indiscriminate demands or are impossible to satisfy.
- **Social Mobilization**, referring to different sectors participation in a variety of activities (such as information, services, persuasion, resources donations) with the objective of achieving common goals.

In view of the above, both the risk information exchange activities and the participation of society sectors can constitute the essence of an effective communication. This is largely due to the fact that we can't presume the public health professionals and other experts think or give their opinion in the same manner as the general public. Information relating to the estimations of risk and its possible consequences, in a communications perspective, and social mobilization, must be covered by precaution, sensitivity and truthfulness, presenting itself in clear terms based on risk assessment, with the purpose of generating the expected positive impact of a well-informed population.

Below, we present some successful factors as mentioned by various authors regarding effective risk communication<sup>8,35</sup>.

- Identify an spokesman to deliver the information
- Know the fact in depth before communication
- Have a well-defined message and adequate communication strategy with the media and affected public
- Generate celerity to give out pertinent information on crisis moments.
- Don't let the political interests overshadow the experts on the matter
- Consider the population as a legitimate partner with voice and vote
- Be transparent and establish relationships of trust
- Aim at dialogue not at the imposition of ideas
- Identify the media work methods and articulate them according to the institutions' needs.
- Sort out the information according to the public
- Share responsibility with the involved parts
- Give out information to the population through clear messages
- Associate yourself to trustworthy institutions
- Reinforce the relationships amongst participants

Finally a good example of successful strategies for the assessment of emergencies is the Field Guide for Developing a Risk Communication Strategy by the Pan-American Health Organization (PAHO), which is a platform that defines, plans and prepares the activities to deal with an emergency. Through this guide, the goal is to joint efforts, optimize resources, strengthen the capacities, establish the different mechanisms of surveillance, define communication channels, collaborators and alliances, manage resources and analyse the possible scenarios<sup>35</sup>. This program specifically focuses on the region's countries in order to create strategies that might be implemented intersectorally.

## INTERNATIONAL REFERENCES OF RISK COMMUNICATION

Before formulating policies and communication strategies, it is convenient to learn that there are international references organisms which have developed guiding principles regarding the matter and that, under different aspects, can help the people in charge for those processes in the government guiding their programs.

For the members of the World Health Organization (WHO), the International Health Regulations (IHR) is the reference when it comes to sanitary surveillance. To the flow of information, IHR establishes that countries designate a National Focal Point, accessible at all times, fulfilling roles of consultation, notification, verification, evaluation and public health response in a coordinated manner with other sectors and authorities in charge of the application of the health measures<sup>35</sup>. The role of these NFP is to receive and release at all times information coming from World Health Organization's Points of Contact, a fundamental action to stay informed and to take the measures in an immediate manner.

Thus, while it is true each country can implement different official mechanisms of risk communication, this Regulation allows the identification of activities and actors, specifying over the release of information to relevant entities of the State administration, including the responsible for the surveillance and the presentation of reports, the points of entry, the public health services, dispensaries and hospitals and other government departments, as well as receiving information from them<sup>36</sup>.

The IHR poses a five stage risk communication strategy which includes: preparation, begin of the public health event, control, recovery and evaluation, where in a special form it is proposed that a working team establish the internal coordination between sectors and with its allies, and formulate a plan for crisis communication and the administration of resources. It is highlighted that, during the preparation stage, it is fundamental to investigate and analyse the possible threats to public health and study the possible scenarios and measures in response to the sanitary emergency<sup>36,37</sup>.

In order to achieve this goal, the development of the risk communication component must be aligned with the national objectives, which is going to allow comprehensively tackling, taking into consideration that there are dimensions and specific factors by country and regions to be taken into account.

On the other hand, for the members countries of the World Health Organization (WHO), there are three international reference organisms which have developed guidelines regarding risk communications: *Codex Alimentarius* Commission, World Organization for Animal Health (OIE) and the *International Plant Protection Convention* (IPPC), where the approach is focused on knowledge and flow of information of sanitary and plant protection interests.

As mention previously, the *Codex Alimentarius Commission* establishes risk communication as a dual channel, impacting the exchange of information amongst the decision makers, the evaluators stakeholders and other groups of interest, emphasizing that it should go beyond of release of information since its main function is to guarantee that during the decision implementation process all information or opinion necessary for a successful risk management be taken into account<sup>7</sup>.

When it comes to the OIE, it uses the same definition stated at the *Codex Alimentarius*. However, the main difference lies in the scope of its application, taking into consideration the decision-making, applied to animal health, especially in the process of importation and exportation of products of animal origin<sup>37</sup>. Finally, the IPPC establishes guidelines for the Pest Risk Analysis, which is the main conceptual model and procedure for the analysis of phytosanitary risks. According to the organization, the central elements of the Pest Risk Analysis (PRA) are risk assessment and risk management, considering the PRA communication as an important step of the process.

## THE ROLE OF RISK COMMUNICATION IN INNOCUOUSNESS

Risk Communication associated to real food danger or perceived ones is an essential component and part of risk analysis process, considering that those in charge of risk management and evaluation should conceive this process as a strategic mechanism to reduce, mitigate or minimize a particular risk.

While the evaluators obtain the scientific data and the managers establish the proper measures, the role carried out by the third party of risk analysis is to consider all the information and pertinent data, identifying and weighing which are the best options to release the information and how to interact with the stakeholders.

When communication mechanisms are established, it is possible to diminish the uncertainty and, as a result, the public trust on authorities can be increased to help put in place the assertive selections, those based on information<sup>39</sup>.

The risk assessment on chemical dangers, for instance, might consider a certain substance as harmful or suitable for human consumption. Nonetheless, with ongoing advance in science and technology it is possible to reevaluate its use. To this regard, the risk communication has a very important role in generating consumer's trust confronting new challenges or knowledge.

Every day, the alert systems report on dangers relating to biological and chemical threats affecting human health, making urgent for the authorities to present well oriented messages, transparent and that doesn't generate any confusion and/or panic on the population which has easy access to the information from any part of the world and in real time.

Studies on consumer's perception of genetically modified organisms, of the "mad cow disease"<sup>15,16,40</sup>, and of the irradiated food shows that the population's perceptions varies according to information around them. An inadequate handling of these can generate great losses to the industry and to the authorities, turning into a barrier to the market. Thus, the importance for the consumers to count on information from trustworthy and reliable sources that address threats and measures.

Consequently, one of the challenges to be faced by Latin American countries and, mainly, South American countries related to risk communication and innocuousness is the strengthening of the surveillance systems, and the definition of roles of the manager and evaluators. These must work in a coordinated way to obtain the information in question. Additionally, they must take into consideration the uncertainty, the ever-changing nature of the information over innocuousness, nutritional aspects, emerging and re-emerging risks associated to food, new technologies and availability of the mass media<sup>39</sup>.

Despite risk communication being a relatively new discipline, the great majority of the developed countries count of risk communication policies and independent organisms that evaluate, manage and communicate risk. Latin American has obviously shown advances in this sense and when it comes to actions. In South America, we must highlight that some countries have incorporated policies and national strategic plans to communicate risks relating to food innocuousness or some initiatives when it comes to this matter.

Chile, for instance, has developed a framework of the Food Safety Program with an action plan to widen and improve the mechanisms of participation and risk communication<sup>41</sup> and instituted a Chilean Food Quality and Safety Agency with the objective of contributing to scientifically based decisions when it comes to innocuousness.

Colombia, for its part, consolidated a National Policy for Agriculture, Livestock and Food Safety for Food Innocuousness to the System of Sanitary and Phytosanitary Surveillance, whose goal is to protect the health and life of people,

animals and plants with focus on the chain that responds to risk analysis. In this regard, the necessity of counting on information exchange actions and opinions from evaluators, managers, consumer and other stakeholders is clear<sup>42</sup>. In response to it, in 2009, the Unity of Risk Assessment on Food Safety to evaluate the risks that the biological hazards might cause biological and chemical dangers of public health interest and, commercially speaking, help the system to take decisions based on scientific knowledge.

Whilst Brazil presents a system for risk communication in sanitary surveillance documented by the Health Ministry<sup>43</sup>, the Peruvian Agro-alimentary Regulation for Safety highlights the implementation of the risk analysis of farming and agricultural primary and imported foods, as well as the communication and national surveillance, the notification of activities that put in risk or have an effect on safety.

Although Ecuador doesn't count on guidelines when it comes to risk communication, this country's Organization Act on the Food Sovereignty Regime highlights the importance of the social participation on the building of public policy proposals.

The previous examples are some of those actions carried out; nonetheless we should highlight that other southern cone countries are starting developing their own initiative and programs, but in spite of its efforts, there is the need to further deepen these actions.

According to the United Nations' Food and Agriculture Organization (FAO) (2007), although there are programs or policies regarding risk communication, in many occasions the personnel in charge are too busy collecting information and taking decisions to dedicate to efficiently communicate risks. Moreover, the cases where there is information exchange, articulations between the evaluators and managers of risk are scarce, where the other stakeholders are involved, mainly the consumers.

In the light of the previously stated, it is important to consider that, since the communication requires knowledge and stakeholders specialized training, which in many circumstances they don't have access to<sup>7</sup>, one of the strategies that could be considered to the countries' better development consists on the exclusivity of the activity, the training of the stakeholders and formulation of policies and programs that respond adequately to the problematic in terms of sanitary surveillance.

## **SOUTH AMERICA'S MAIN CHALLENGES IN RISKS COMMUNICATION**

Even though in South America there are advanced processes on risks communication in sanitary surveillance, it still necessary the articulation among risk evaluators and managers, in such manner that the scientific knowledge generated by the former allows actions and measures to be adopted by the risk managers are adequately oriented.

In turn, it is important for the policies formulated to involve the citizen's participation and that bounds are generated with the media so they act as facilitators for the process during the communication of the results of the management carried out by the health authorities.

Any political initiative in this sense should be based on trust and authorities shouldn't be limited solely to releasing the message, but also make an effort to give out clear and transparent information that doesn't generate contradictory messages, and therefore, non-compliance of the control measures.

Countries should count on local and national risk communication programs that comprehend: planning of activities, interaction among institutions and the community through an adequate inter-institutional coordination. The previously stated could be implemented in a country level perspective, where after a national policy, both the realm of action and the institutions' different roles, as well as mechanisms of citizen participation, communication channels, etc.

After assessing the previous overview, we can't ignore the importance of the risks communication as a key element empowering societies in the quest for equality, justice and transparency. Risks communication, as a challenge, is developed in a complex framework. For that matter this discipline has to be thought today after the meeting and socio-cultural diversity, from the change to transformation, especially on Latin American countries.

Finally, Latin American countries pave a way to dialog, the resolution of conflicts, trust amongst all parts, especially among the government staff, scientists, the industry and the consumers. But, above all, the challenge is to generate instruments with which risks communication can be addressed from a new paradigm, a place where different nations are brought together to identify their problems and generate joint strategies towards a harmonized sanitary surveillance risks communication and coherent to the needs and problems of our continent.

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## V. International cooperation and interaction of the UNASUR regulatory authorities within the south american health care systems

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### INTRODUCTION

**T**he public health's approach to the regulatory field, particularly in sanitary surveillance, when is linked to risk control and mitigation, it should go beyond any assumptions that solely relate the health of individuals and populations to aspects of social and economic development. Regional, geopolitical, cultural and structural aspects should also be considered as a daily task for every health authority, having cooperation between countries as their corner stone<sup>1</sup>.

Throughout the last decades the intensification of people and goods mobility has increased the chances of populations being exposed to potential health risks, plus imposed additional responsibilities to the health authorities in their efforts to protect human health and guarantee the safety and efficiency of goods and services.

Due to this current global scenario, governments and health authorities of all over the world have started to experience an increasing number of situations that require integrated response between countries. These globalized and increasingly intense changes have been altering the national demographic bases. Likewise, when associated to the ever increasing competitive environment, determined by the innovation, plus the products increasing technological volatility and complexity, these changes intensify the demand and pressure upon regulatory authorities. Thus, establishing more adequate protection patterns in responses and actions becomes increasingly necessary.

This situation can be observed in the changes of the global economy dynamics and the expansion of the countries participation in the processes of production and global consumption, including drugs, medical devices and other health related products. The production chains have been internationalized. Nowadays, a drug can be developed in a certain country, but its clinical research is conducted in a second country, its active component is produced in a third country, but its industrial



manufacturing is led in a fourth country while consumption occurs in several others. Thus, the same product is subject to regulation by several national authorities, either in the stages of research, development, production or consumption.

Such aspects contribute with the dilution of borders and establish both the health of individuals and populations as a strategic point to all nations. In this regard, it should stimulate the understanding that regulatory action and global surveillance is an urgent need for facing challenges both at regional and, primarily, at a global level. This understanding is related, primarily, to the commitment and responsibility of all jurisdictions for strengthening mechanisms of control and surveillance.

On the other hand, decision-making by regulatory authorities foregoes more and more a multidisciplinary and intersectoral assessment in a wider and more agile spectrum.. This evaluation must weigh the risks involved, their impact, the best ways to communicate with the population and the productive sector, and the need to constantly expand regulatory actions.

Governments and health authorities in several regions of the world have faced the increasing challenges in finding ways to promote the contribution and optimization of the expansion of knowledge, financial and human resources, and the balance required to access goods and services with quality and safety.

## THE INTERNATIONAL SCENARIO

Recent events such as the outbreak of bird flu and pandemic influenza, quality deviations as in the case of breast implants, dairy products adulterated with melamine and counterfeit drugs, bring to light the urgent need for greater integration in regulatory efforts, taking into account the health impact that goes beyond borders.

Therefore, there is an opportunity to identify new ways of coordination that can go beyond a simple harmonization or standardization of regulatory frameworks. Thus, a global surveillance system can be set on the recognition and increasing capacities of national authorities, and build a relationship of mutual trust based on common principles. This system must induce synergistic actions between authorities whose attributions are already established, and also be able to support the countries and authorities that are striving to develop their capacities.

The exchange of information, sharing of experiences and the development of joint activities has shown results in the achievement of a greater synergy in health regulation and the protection of the health of the populations, and there is opportunity for expanding these actions. Certain concrete demonstrations on how to cooperate in areas of growing importance and international visibility should be remarked. Among many others, we should mention the initiatives taken by the International Conference of Drug Regulatory Authorities (ICDRA), the actions

developed by the World Health Organization and the Pan-American Health Organization (PAHO), the Regional Office for Europe; the joint efforts in the certification system for products purchased for international programs, and the Pharmaceutical Inspection Cooperation Scheme (PIC/S).

Another example was the support provided by WHO for the organization of the International Conference “Health Security - Challenges in a borderless world: cooperation between drug regulatory agencies”, sponsored by Brazil and held in Geneva, in the context of the 65th World Health Assembly, in May 2012. This event provided the opportunity to show the coordination between different regional initiatives, identify new ways for bilateral cooperation, and improve communication and information exchange within the scope of the WHO and its regional offices. The Conference, which was attended by representatives from more than 50 countries and several international organizations envoys, was established as a starting point for discussion and deepening of all joint actions aimed to help the health authorities in meeting their national goals in order to ensure the security of goods moving in and out of their territories. It was also a great opportunity for interaction with non-governmental organizations that have had the experience of expanding their markets globally. Thus, the support of multilateral institutions such as WHO and PAHO has growing importance for creating greater convergence between all the work and initiatives that have been conducted around the world.

There are currently numerous experiences of efforts integration, with good examples of initiatives that generate significant results, such as the many movements oriented to regulatory convergence, the promotion of information exchange and the development of joint efforts. Altogether, they allow to exploit new, more effective and integrated forms of cooperation. Therefore, we must think in a performance capable of enhancing and optimizing all these efforts, but avoiding the duplication of initiatives.

## **THE PERFORMANCE OF UNASUR**

In 2009, the Union of South American Nations (UNASUR) created the South American Health Council (UNASUR-Health) to discuss issues related to integration and cooperation in health in South America<sup>2</sup>. In this way, the recognition, use and development of skills within the health regulation and control field may represent the great existing solidarity between these countries in order to take care of the health of their populations.

Considering the peculiarities of local and regional structures, the evolution of the cooperation levels should be designed after considering those differences in order to produce results that can be reflected in the achievement of an adequate level of protection.

The concept of “adequate level of protection”<sup>3</sup> seeks to establish a corner stone from which can, in fact, be reflected the commitment and efficacy of national sanitary surveillance structures, which also allows managing and reducing risks, in the proportion that they are imposed, on a proven joint work.

Each regulatory system and jurisdiction should have the ability to make and establish their own technical requirements, rules, regulations and procedures, as well the ability to set and monitor the implementation of these regulations by performing a set of surveillance activities and actions.

Forums like the meeting of Presidents of Drug Regulatory Agencies emerge as major promoters of that debate, as well as builders of new efficient and durable paths. Regionally speaking, the Technical Groups and Institutional Networks (I) of the UNASUR-Health are not only contributing to the improvement of national systems through the exchange of information and experiences, but had also helped in coordinating strategic positions during international forums.

The strengthening of this coalition mechanism, which is based on mutual trust, transparency, and in sharing challenges, is established as a practical and inclusive model that promotes innovation and the development of regulatory capacities and benefits from the abilities already established.

Therefore, the dissemination of knowledge concerned to national regulatory structures and current regular initiatives become essential in order to build solid levels capable of extending the supporting mechanisms for sanitary surveillance measures at both regional and global levels.

The UNASUR-Health member countries are undertaking initiatives in this regard, such as the first workshop on “Sanitary Surveillance Systems in South America” (II), held at the headquarters of ISAGS, in October 2012. The main objectives of this workshop were to strengthen the health authorities of UNASUR by acknowledging the structures and requirements of the health regulatory and surveillance systems of each country, whilst promoting the exchange of experiences and a systemic reflection on the subject.

Thus, and based on some pre-established topics, the methodology consisted of each country presenting different aspects such as: structure, organization and capacity, macro management, workforce, number of employees and work training, performance by areas, and research and innovation in surveillance. Besides that, it was considered appropriate to guide countries into the analysis focused on possible weaknesses and strengths, pointing out the needs and possibilities of cooperation. The disclosure and discussion of specific cases of success and challenges experienced by the countries were the basis for discussion and development of a joint work plan that should be considered by the UNASUR-Health/ISAGS when it comes to set priorities.

In this way, the workshop contributed greatly to the expansion and mutual understanding of the sanitary surveillance systems and structures within the region, and to identify ways for cooperation, which will allow a better approach of ISAGS' strategic objectives through the development of actions seeking to implement the work plan agreed between countries. We must emphasize the promotion of studies in order to explore different solutions to the problems faced by the health authorities of the region, taking into account the need of rationalizing the actions and optimizing resources; promoting the training of professionals working in the sanitary surveillance field as well the exchange of experiences in the continuing use of different education methodologies. The afore mentioned actions have the intention of facilitating the union of countries in order to promote horizontal cooperation in accordance with the strategic guidelines set to address the weaknesses identified within the region.

The relevant issues considered and debated included: regulation harmonization, evaluation and incorporation of technology, international certification of manufacturers of health strategic products, exchange of international inspection reports, quality control and human resource training. Likewise, other highlighted topics were those of medical devices seen as an urgent and general need in order to work together with the issues raised, plus discussions on medicinal plants and pricing policies. Another issues remarked were those concerning technological surveillance and pharmacovigilance, as well risk analysis in all its aspects with emphasis on risk communication and systematic and dynamic communication in order to increase the exchange of information and the effectiveness of sanitary surveillance activities among the countries in the region. In addition, the role of advertising and the media related to Sanitary Surveillance interests were discussed as well.

UNASUR-Health emerges as an integrator and developer of cooperation among member countries. ISAGS provides an important collaboration as it supports the participation of the regional health authorities in conferences and meetings of interest to surveillance and, consequently, in the making of global outlines on the subject.

Several ongoing work fronts, which are represented by bilateral cooperation initiatives already formalized and developed among the countries of South America, are presented as platforms that can be amplified to the rest of the UNASUR members. In this field, we must emphasize the initiative intended to share experiences and build abilities in order to create a UNASUR's Regional Pharmacopoeia, as well the exchange of surveillance experiences at countries' border lines, prevention and fight against counterfeit drugs, price regulation, social participation, regulatory agenda, and drugs regulation.

## CONCLUSIONS

Reducing risks and promoting the development of global regulatory channels, which are consolidated around a synergistic vision, and capable of increasing the actions of protection and promotion of human health and life quality as well providing a higher efficiency, are the objectives to be achieved.

The regulation and monitoring of goods and services cannot rely on isolated actions conducted by national authorities as regulators, the countries' responsibility for protecting the public health transcend all borders. It is important to say that the support provided by existing international institutional structures is essential to implement the aspirations of a greater exchange of information and experiences. Especially PAHO and WHO have technological and human resources that are already structured and can greatly help the countries in the region with the improvement of health regulatory structures. What becomes essential is for countries to be able to manage and address these existing resources in the best way possible in order to meet both national and regional needs. This is a primary task and one that UNASUR-Health/ISAGS has been constantly promoting in order to consolidate the regional integration.

The global changes push for global solutions within the health field. Likewise, these changes demand some global, sustainable, and inclusive actions capable of ensuring the continuity of the debates and, at the same time, transforming them into a more efficient and articulated work.

It is possible to build different ways of action in which new global agreements can innovate the regulatory, monitoring and control activities that will emerge to become an effective platform for collaboration, with results that live up to and match the growing challenges faced by regulatory agencies. Plus, these results must contribute to the establishment of higher levels of international protection and access to goods and services, as another strategy to promote global health.

It is well known that no authority can face this challenge alone. Coordination and exchange of information along with the flow of technical expertise and the cooperation in the building of national structures, with all due respect to national characteristics, are pillars in overcoming this challenge. Improving the health status of the countries is a possible goal, while the union of peoples and the continuous dialogue forums constitute some highly efficient means for achieving this goal so that benefits could not only be enjoyed by the country that improved its condition, but also by the region where the country is located. Hard work should never stop, because only then we shall achieve the much dreamed consolidation of health integration.

The financial support of the countries in the region is strategic as it enables their participation in key global discussions that affect all drug regulatory authorities, besides the fact that it enables the interaction between these agencies, the exchange of information and experiences and the deepening of regulatory dialogue and mutual trust. And finally, the interaction between these authorities is what makes possible the realization of joint works, regulatory convergence, and making decisions together.

It is necessary to move forward in building a regional and global coordination between regulatory authorities, governments and multilateral cooperation organizations, being the focus set on global changes and trends as well on the search for global solutions in order to increase the ability of protecting the individuals health, wherever they are.

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## NOTES

- I - The institutional Networks and Technical Groups that are part of UNASUR-Health are, as follow: National Health Institutes (RINS), Public Health Schools (RESP), Technical Health Schools (RETS), National Cancer Institutes (RINC), International Relations in Health (ORIS); and the Technical Groups: Health Surveillance and Response, Development of Universal Health Systems, Universal Access to Medicine, Health Promotion and Social Determinants, Development of Human Resources Management
- II - For more information on the Workshop “Sanitary Surveillance Systems in South America”, visit [www.isags-unasur.org](http://www.isags-unasur.org).





## VI. South American Network of Health Surveillance and Response: creation, agenda and challenges

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### INTRODUCTION

**T**he fundamental framework of the health surveillance integration process took place during the UNASUR's second summit for Heads of State held in Cochabamba (Bolivia) in December 2006<sup>1</sup>. At that time it was defined the “*creation of a South American network of public health surveillance and control, which sets regional vaccination programmes and the development of projects for the joint purchase or production of essential drugs and vaccines*”<sup>2</sup>.

The building process for a South American network of health surveillance and response had its start after two sub-regional initiatives: the Health Surveillance Committee of the Working Subgroup 11 “Mercosur-Health” (Mercosur), and the Andean Epidemiological Surveillance Network of the Hipólito Unanue Andean Health Agency (ORAS-CONHU).

As part of the Mercosur, the Health Surveillance Committee began its activities in 1998 and was originally called Epidemiological Surveillance and Health Control Committee of Ports, Airports, Terminals and Borders<sup>3,4</sup>. The Committee's main role is to define and propose the harmonization of epidemiological surveillance processes and tools, which include preparing a list of communicable diseases, their definitions, diagnosis, prevention and control measures, create an information system, establish reporting flows and tools, and inform of all events that may constitute a public health emergency. Furthermore, the Committee has the attribution to harmonize sanitary control measures at international entry points as well on all transportation services working in these areas. Representatives of the following nation members have participated in the Committee so far: Argentina, Brazil, Paraguay, Uruguay, and Chile being the latter an associate member.

The emergency caused by the arrival of “El Niño” weather phenomenon to the Andean region, represented the trigger to create the Epidemiological Alert

and Surveillance Network, which was later renamed as “Andean Epidemiological Surveillance Network” (RAVE in Spanish).

Its creation aimed to meet the concerns of the health authorities in knowing the impact that “El Niño-Southern Oscillation” weather phenomenon would have on the population in 1997 and 1998, since the previous experiences of 1982 and 1983 generated some dramatic changes in terms of morbidity and mortality caused by communicable diseases, especially those transmitted by vectors, animals, and human to human, causing an increase in respiratory, digestive, skin, immune preventable, vectorborne and zoonotic diseases in the countries affected by these rains and floods.

The RAVE is composed by six member countries (Bolivia, Chile, Colombia, Ecuador, Peru and Venezuela), and was created in 1998 when it reported 14 diseases to ORAS - CONHU (diphtheria, rubella, measles, pertussis, hepatitis B, canine and wild rabies, classic and hemorrhagic dengue, *Plasmodium vivax* and *falciparum* malaria, yellow fever, plague and cholera)<sup>5</sup>.

Starting in 2004, the Andean and Mercosur nations have been discussing health surveillance, particularly during the reviewing and approving process of the International Health Regulations (IHR 2005), which are described below.

To achieve a real articulation of the existing health surveillance networks in South America, a process between the Ministries of Health of the Andean and Mercosur countries started in 2007 with the intention of strengthening and harmonizing a common criteria for the identification, reporting, control, response and prevention of diseases prioritized by those networks.

During the VI Andean Forum of Epidemiological Surveillance and Border Health, held in Lima, Peru (March 2007), many integration agreements between the countries of the Andean and Mercosur networks started to be discussed in order to define a common agenda including the top-priority existing issues between the two blocs<sup>6</sup>. During this meeting, the IHR was proposed as the proper framework in which the bloc’s common agenda should be based on and debate. The topics proposed were:

- A. Harmonization of surveillance and response tools and processes: definition of top priority health events; definition of information exchange tools and processes, establishment of guidelines and standards for clinical and laboratory diagnosis, prevention and control measures, organization of actions; monitoring and evaluation indicators.
- B. Exchange of public health emergencies information: definition of the top priority diseases within the region, the use of the decision instrument for evaluating national emergencies, to share experiences on the use of the decision instrument, communication and analysis of regional public health emergencies; and supporting joint interventions.

- C. Strengthening the basic surveillance and response capacities: use of a basic and unified assessment instrument; exchange of assessment experiences, joint developing of capacities, establish plans to strengthen new capacities, identify funding sources, develop and implement contingency plans.

During the Meeting of Ministers of Health of Andean Region held in March of the same year in Santa Cruz de la Sierra, Bolivia, and based on the proposals presented at the RAVE meeting, it was agreed to: “Establish the basis towards the creation of a South American public health surveillance and response network to harmonize instruments and procedures with the technical cooperation of the Pan American Health Organization (PAHO)”<sup>7</sup>.

In March 2008 the VII Andean Forum of Epidemiological Surveillance and Border Health took place. The event served as another opportunity to continue debating the integration process, and establishing the ways to make a joint diagnosis of the countries’ core capacities for surveillance and health response as stated during the 2005 IHR<sup>8</sup>. Likewise, these same topics were addressed during the VIII Andean Forum of Epidemiological Surveillance and Border Health held in March 2009, when the focus was set on harmonizing all surveillance instruments and procedures within the South American network<sup>9</sup>.

These two meetings were integrated to the Andean and Southern Cone Emerging and Re-emerging Infectious Diseases Surveillance Networks created by the Pan American Health Organization (PAHO). The PAHO’s initiative supported the collaboration between the two sub-networks for the creation of a South American Surveillance and Response Network.

Table 1 – South American Health Surveillance initiatives before South American Health Surveillance and Response Pre-Network

Year	Place	Events
2005	Montevideo, Uruguay and Buenos Aires, Argentina	Coordination meetings for joint actions on the IHR revision.
2007	Lima, Perú	VI Andean Forum of Epidemiological Surveillance and Border Health
2007	Santa Cruz de la Sierra, Bolivia.	XXVIII Andean Region Health Ministers Meeting
2008	Caracas, Venezuela	VII Andean Forum of Epidemiological Surveillance and Border Health, and Sub Regional (Andean and Southern Cone) Meeting of Emerging Infectious Diseases Surveillance
2009	Asuncion, Paraguay	VIII Andean Forum of Epidemiological Surveillance and Border Health, and Sub Regional (Andean and Southern Cone) Meeting of Emerging and Re-emerging Infectious Diseases Surveillance

Source: Elaborated from oficial documents of the corresponding meetings.

## CREATION OF THE SOUTH AMERICAN HEALTH SURVEILLANCE AND RESPONSE NETWORK - UNASUR HEALTH

In 2008 there were three important meetings that consolidated the creation of an UNASUR's South American Health Surveillance and Response Network, as it had been proposed in previous technical and political stages. The following events: UNASUR's Heads of State and Government Summit held in Brasilia, Brazil, in May<sup>10</sup>, the UNASUR's Ministers of Health Summit held in Rio de Janeiro, Brazil, in November<sup>11</sup>, and the UNASUR Presidential Summit held in Salvador, Brazil in December<sup>12</sup>; established the Unasur-Health's working plan and included it as one of the five technical groups set to accomplish this plan that was then called "South American Epidemiological Shield". The main goals set for this particular group were: articulating the surveillance and response networks of all Member States in accordance to the IHR, the early detection and response in case of outbreaks, and the elimination of communicable diseases<sup>13</sup>.

All the guidelines for the 2009-2010 Work Plan were approved, while the respective coordinators were designated during the Meeting of the Constitutive Council for the UNASUR South American Health Council celebrated in April of 2009 in Santiago de Chile. It was also an opportunity to initiate this political space integrated by the bloc's Health Ministers.

The "Epidemiological Shield" technical group, whose coordination was in charge of Paraguay, would include the following initiatives: developing a South American epidemiological surveillance policy; establishing a registry of regional morbidity and mortality standardized indicators based on the Millennium Development Objectives, promoting the joint efforts in the prevention and control of diseases in border areas: creating, strengthening, consolidating and articulating the South American epidemiological surveillance and control networks; preparing a report identifying all top priority diseases to be addressed at a South American level, and promoting a regional immunization programme.

In November 2009, the UNASUR's South American Health Council met in Guayaquil, Ecuador<sup>15</sup>, and decided for the development of a Five-Year Plan (2011-2015) whose final guidelines were set at the meeting held by the South American Health Council's Coordinating Committee in March 2010 in Rio de Janeiro, Brazil<sup>16</sup>, and approved during the Council's meeting celebrated in April of the same year in Cuenca, Ecuador<sup>17</sup>.

This Five-Year Plan was based on the proposals presented by the Technical Groups, including the Epidemiological Shield. This group held its first meeting in Asuncion, Paraguay, in June 2009<sup>18</sup>, where they established the proposals for this specific working area that would then be presented during the Coordinating

Committee's meeting celebrated in Rio de Janeiro<sup>16</sup>. During the first meeting of the Technical Group, it proposed to change the name "Epidemiological Shield" to "South American Network of Health Surveillance and Response", considering that the latter meets the objectives of working under a network strategy and gathers the contributions of other sub-regional units (Mercosur and Andean Epidemiological Surveillance Network) that were already working on these issues<sup>18</sup>.

The expected results for the South American Network of Health Surveillance and Response's Five-Year Plan are: a) R1 - to select indicators of regional morbidity and mortality risk factors; b) R2 - to create an information system for reporting prioritized diseases in the region. This system must represent all national and sub-national levels (VIGISAS/RAVE); c) R3 - to create a monitoring and assessment system for the implemented Surveillance Network; d) R4 - to establish basic surveillance and response capacities for dealing with National and International Health Emergencies (ESPIN and ESPII, respectively, in Spanish), always implemented in accordance with the International Health Regulations (IHR); e) R5 - to set an operating UNASUR-Dengue Network to mitigate the impact of dengue fever in the region; f) R6 - to set regional strategies for the prevention and control of noncommunicable diseases; g) R7 - to promote a South American immunization programme<sup>17</sup>.

The activities planned by the Surveillance Network were based on the regional top-priority health issues. Thus, chronic noncommunicable diseases represent a heavy burden in terms of morbidity and mortality for South American countries, and have a great impact on the health of the poorest populations. In terms of communicable diseases, the dengue fever is one of the most important issues to be faced, as it is present in most countries of the region. It still is a very relevant topic in the on-going political agenda of all regional ministers. Likewise, points R1, R2 and R3 of the Five-Year Plan are related to the need of having common instruments and tools for the exchange of information between countries as this will allow to know the region's health situation so that countries could work together on the top-priority issues. The IHR item, as it will be discussed below, represents an opportunity to develop health services and establish cooperation between countries in order to provide timely responses to public health emergencies.

## DEVELOPMENT OF THE SOUTH AMERICAN NETWORK OF HEALTH SURVEILLANCE AND RESPONSE'S FIVE-YEAR PLAN/UNASUR-HEALTH

During the second summit of the South American Network Health Surveillance and Response held in Brasilia, Brazil on August 5, 2010<sup>19</sup>, all the implementation strategies for the Five-Year Plan were analyzed, plus the Five-Year Plan for dengue fever prevention and control proposed by the national coordinators of the South American control programmes was shared with the audience. Likewise, it was agreed that the national focal points would be responsible for the promotion of the Five-Year Plan in each country. Also, all mechanisms for coordination and monitoring of the Plan activities were established during the summit.

The third summit of the South American Network Health Surveillance and Response was held in December 2010 in Quito, Ecuador, and organized along with the IX Andean Forum of Epidemiological Surveillance and Borders Health<sup>20</sup>. The summit was framed within the guidelines established for the UNASUR-Health's Five-Year Plan. During the summit, the need to implement a single notification tool for prioritized diseases was discussed along with the establishment of a single list of interests which should include 14 events under surveillance in the South American countries. It was also established the need of setting an activities schedule for 2011 as well designating the agencies responsible for accomplishing each result. Thus, the Network's national coordinators were assigned with the responsibility of taking all the measures specified in the Plan for reaching results 1 to 4. Meeting the R5 (dengue fever) expected result would be direct responsibility of the Programme's national coordinators, which should also designate the focal points and those responsible for the monitoring. In order to meet expected results 5 to 7, the summit also identified the need for the South American Health Council to constitute technical subgroups, plus the designation of focal points to develop the 2011 schedules, and the establishment of a tracking system for the specific topics discussed.

The fourth meeting of the South American Network Health Surveillance and Response, held in May 2011 in Montevideo, Uruguay, along with the X Forum of Andean Border Health and Surveillance<sup>21</sup> was focused on discussing the International Health Regulations due to the need of their implementation within the region. It was also addressed the need for revision of the World Health Organization's instrument developed to monitor the basic capacities provided in the Annex 1 of the 2005 IHR. Plus, in relation to the surveillance and response component (Annex 1A), it was defined the use of the Mercosur's instrument that was adopted for conducting an initial assessment of their basic capacities. During the summit it was also decided to take to the WHO the proposal of migrating all Mercosur instrument's data to the instrument developed by the WHO. Thus, the information of the South American

region that would be used by WHO on its annual World Health Assembly (WHA) report, should also take into account the data migrating process between the two instruments conducted through PAHO. Furthermore, the component of the instrument used to monitor capacities related to international entry points was not used by the countries as it was considered insufficient to reflect the degree of progress of these capacities in the countries of the region.

At the 5<sup>th</sup> Meeting of the South American Network Health Surveillance and Response held in Montevideo, Uruguay, in August of 2011<sup>22</sup>, the main topic of discussion was still the preparation of a report on the implementation of the IHR, and the development of the core capacities as provided in Annex 1. Likewise, they kept insisting on the need for having a migration tool in order to bring the Mercosur's instrument in to the WHO's questionnaire. Plus, it was defined to send the annual summary report on the IHR implementation status to the WHA in a format that captures all Mercosur indicators (along with the migration Excel spreadsheet), so that it will allow WHO to update its database through PAHO. Regarding the international entry points, it was decided to transfer, as part of the IHR implementation reports, to the WHO all information regarding the assessments conducted on international entry points basic capacities as established by type of entry points and defined capacities following Mercosur's tools, divided into communication, routine and emergency. These strategies enabled to capture the most relevant information about the real level of progress showed during the implementation of the IHR in accordance with the specific health systems of the countries of the region.

In order to fulfill the agreements reached during the third Network's meeting, the representatives gathered during the Fifth Meeting proposed the creation of a specific immunization working group, consisting of the heads of the Immunization Programmes in order to develop a work plan which would include as its first challenge the elimination of measles and rubella, thus integrating the existing initiatives in the region. It was also agreed that the plan should be presented to the Network during its 2012 first semester's meeting.

Regarding non-communicable diseases surveillance, it was agreed the need for coordination between Mercosur's NCDs technical group and RAVE in order to reach consensus on the indicators established for these particular diseases and through the guidelines set by the South American Network of Health Surveillance and Response, thus meeting the goals set for the Five-Year Plan. Likewise, Emergency and Disaster surveillance was indicated to be included as an Andean countries specific topic of planning to be treated during this region's Health Ministers meeting. In addition, its inclusion on the list of activities of the UNASUR-Health's Five-Year Plan through the technical group created for this specific matter was also proposed.

## IMPLEMENTATION OF THE IHR (2005) IN SOUTH AMERICAN COUNTRIES

The assessment of basic capacities in accordance to Annexes 1:A and B of the Regulations started right after the 2005 IHR became effective. Likewise, and thanks to the cooperation of both Mercosur and PAHO, an instrument was developed in order to assess basic capacities. Plus this instrument was shared with all South American countries, thus they could use a single instrument for the entire region between 2008 and 2009. This same instrument was also used in 2011, to monitor the progress of the IHR implementation, which was then used by WHO for the preparation of the 2012 annual World Health Assembly's report<sup>21,22</sup>.

In the first IHR's core capacities assessments conducted by all the countries of the region until 2009, it was found that there were many gaps to be filled to achieve the basic capacities planned for 2012, especially with regard to the basic intervention capacities on public health emergencies<sup>21</sup>. However, when comparing the initial situation with the most recent results showed in countries that conducted a reassessment in 2011, it appears that there has been progress in many areas, thus expanding the capacities to intervene on public health emergencies.

Among the common problems the countries show in order to fulfil the action plans that were developed after the assessment of basic capacities, we must remark the need for strengthening the intersectoral efforts. This strategy should go down on to the local level, allowing the participation of other sectors and developing all required capacities for dealing with public health emergencies.

It was also identified a lack of qualification within the health professionals, a situation that requires the development of training plans in various areas, particularly in the one related to international entry points.

The effective implementation of the IHR in the region is difficult as there still are constraints in order to achieve a great heterogeneity among countries. This may generate some difficulties in terms of having a common instrument for monitoring the implementation of the IHR within the region. It also identified the need to raise the IHR issue into the areas where political decisions are made in each country. The insertion of the IHR at political decision levels is considered as an important strategy to expand the financial resources needed for developing the countries' capacities. Regulatory constraints were also identified in many countries, something that brings up the need of reviewing and improving, where indicated, national laws and regulations. Furthermore, weaknesses in the information systems were spotted as well as very little development of the monitoring and evaluation activities. Because of this, South American countries should run a review of their current information exchange and joint analysis processes in order to have a regional perspective on what the major health problems are and enable greater cooperation for resolving these problems.

## **SOUTH AMERICAN NETWORK OF SURVEILLANCE AND RESPONSE'S IMPROVEMENTS**

The Mercosur and RAVE sub-region initiatives were previously developing some health surveillance activities included in the Five-Year Plan. Following R2 expected results (creating an information system for reporting prioritized diseases in the region), there is already available an information system (VIGISAS) developed for the UNASUR member countries<sup>20</sup>. This system's latest version, called VIGICONHU2, was developed by the Andean Epidemiological Surveillance Network (RAVE) in order to exchange information on top-priority communicable diseases. All data regarding communicable diseases can be uploaded to the system from the national databases of each country (which are built on different platforms). Likewise, it uses the different territorial divisions (called NUTES ) as units of analysis. A memorandum of understanding signed between the Andean Health Organization-Hipólito Unanue, and the Mercosur's Health Ministers in November 2008 in Rio de Janeiro, Brazil, allowed to transfer the system's technology to the entire Mercosur so that information could be managed at a regional level by all the South American countries<sup>23</sup>. Thereafter, Brazil's National Health Coordination Unit for the Mercosur along with its Joint Unit for Health Information & Communication Systems Operations, which is responsible for the management of the system, made the necessary improvements needed by the system in collaboration with RAVE. Likewise, they supported its implementation in the South American countries that were involved in the data migration process.

Another task conducted by the two regional sub-blocs in relation to the use of the VIGISAS system was the harmonization of the lists of diseases to be included in the system for notification. Given that Mercosur and RAVE used to adopt different diseases for their regular exchange of information, it was then agreed to make a single list for the entire South American region. This decision was approved in April 2011 through a UNASUR's resolution<sup>24</sup>. The resolution also approved the inclusion of noncommunicable diseases indicators in the VIGISAS.

Regarding to the expected result 4 (establishing basic surveillance and response capacities before ESPIN and ESPII and in accordance with the 2005 IHR), all member countries have worked together since the early implementation stages of the Regulations in order to achieve the use of a single and unified procedure for monitoring and reporting the advances made in the development of basic capacities. As mentioned before, all gathered information was then used by WHO to prepare its Global Report in June 2012<sup>21,22</sup>.

Furthermore, an information system called SIME (Event Monitoring System), which monitors events that may constitute a public health emergency of national

or international concern, was developed. This system was developed by the Health Ministry of Brazil through its Health Surveillance Strategic Information Centre. It was based on a Technical Cooperation agreement between Brazil's Health Ministry and PAHO that was signed during the PAHO's Executive Council meeting conducted in September 2010. This system has also been adapted by other countries in the region<sup>25</sup>.

## **SOUTH AMERICAN SURVEILLANCE AND RESPONSE NETWORK CHALLENGES**

Considering the developing activities led by the South American Network of Health Surveillance and Response, we can identify some needs to boost its top-priority challenges.

Based on the definitions of communicable diseases that will be part of the regular information exchange between countries in the region through the VIGISAS computerized system that allows data analysis under a regional perspective, it becomes necessary to consolidate the creation of Surveillance Guidelines containing all common definitions and procedures for disease monitoring and control. These activities have already been initiated by the Mercosur and RAVE sub-regional blocs, based on their existing experiences.

Unlike the Andean countries that use this system to exchange information with the support of RAVE, the current effective implementation of VIGISAS among Mercosur countries has been very heterogeneous. Thus, the system has not yet met the expectations for which it was conceived. Anyway, new opportunities loom on the horizon. Thus, and during the Mercosur's Health Surveillance Committee meeting conducted under Argentina's last Mercosur pro-tempore presidency term (first half of 2012), it was put in the agenda and approved by the Common Market Group the hiring of professionals to exclusively manage the VIGISAS in order to reach its full implementation<sup>26</sup>. Measures like this, set a potential framework in the use of the region's Surveillance System.

With regard to non-communicable diseases, the activities carried out by the UNASUR are limited to the exchange of communications on country experiences in reference to the monitoring and control of these type of diseases. Thus, in order to make progress on this issue, it is necessary to define a region's common agenda and strategy by using the experiences of the sub-blocs. Likewise, it should be noticed that the VIGISAS allows to entry data of specific noncommunicable diseases, although it has neither been defined which type of data (or indicators) must be entered nor the procedures to be followed for data collection. For immune-preventable diseases, for which measles and rubella have already been established as the top priorities, it was identified the need to develop and meet a working

agenda as from 2012 considering the region's goal, which consists of eliminating the aforementioned diseases.

With regard to the monitoring and control of dengue fever, plus considering that some of the objectives set for the Five-Year Plan are related to this topic -especially in terms of information exchange between countries- it was identified the need for establishing closer coordination between the existing technical subgroup and the South American Network of Health Surveillance and Response. This issue was also treated by the Unasur's National Health Institutes Network when related to materials and diagnostic tests or kits needed for diagnostic and research. The RAVE has recently defined a work plan for controlling this disease, giving priority to the reduction of mortality within the sub-region, which can be extended to the entire South American region<sup>27</sup>.

The IHR (2005) is definitely one of the most discussed and developed issues within the Network, though it is necessary to promote cooperation strategies based on the identification of gaps during the basic capacities assessment and monitoring processes, and the difficulties already diagnosed by countries during the implementation of the Regulations. Similarly, they should work on the use of screening and communication tools for urgent events, thus exercising a regional perspective for such events with the objective of not only sharing information about the events that may occur in the countries of the region, but also learning from the experiences of these countries.

Some topics that are part of the agenda were not yet debated, as for instance risk factors indicators (R1), as well the monitoring and evaluation of the Network itself. These issues represent a central component in terms of Health Surveillance strategies and policies, plus they have a great development within the countries in the region. Sub-regional and national experiences can be used to start developing these issues within the UNASUR's framework, as well as establishing a coordination plan with other working groups, as for instance on social factors, as well with the National Health Institutes' Network (RINS)/UNASUR.

There are also topics of discussion concerning the Network's competences that even though they are not part of the Five-Year Plan, they make an important part of the health surveillance competences. One of them is that concerning public health laboratories, for which a interface connection must be established must be established with the RINS. The Mercosur has already begun to address this issue, and defined the creation of a specific working group that will interact with the bloc's Health Surveillance Committee. All environmental disasters and risks related issues have not yet been included in the agenda, though all required preparation actions for facing a natural disaster are already being worked by a specific group that has been created at the UNASUR. Likewise, all violence related issues, which translate into high morbidity and mortality rates within the region, have not been included

as part of the discussion on non-communicable diseases. Furthermore, the worker's health is another issue that has not been discussed so far by UNASUR-Health's technical groups. Finally, all sanitary surveillance as well health goods and services regulations related issues that are currently discussed in other technical groups (universal access to medicines, health promotion, actions on social factors, and food safety, among others), deserve to be discussed by the South American Network of Health Surveillance and Response, in particular those involving international points of entry, which is an important issue in the Mercosur's Health Surveillance working agenda, and is fundamental for the appropriate implementation of the IHR in the region's countries.

The South American Network of Health Surveillance and Response has a triple challenge: meeting its agenda's objectives by reinforcing the well developed topics; expanding its agenda on issues that have not yet been discussed, and including, in coordination with other groups and networks, all issues or activities that are part of the health surveillance field. Our region's strength is based on the fact that for these topics there have been successful experiences in the countries that need to be known, disseminated and integrated.

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## VII. Disaster risk management in the framework of UNASUR Health

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### INTRODUCTION

In the last few decades, emergencies and disasters in the countries have considerably risen. Losses caused by disasters and recovery costs have also increased substantially. According to 2011's Global Assessment Report on Disaster Risk Reduction, elaborated by the United Nations International Strategy for Disaster Risk Reduction (UNISDR), disaster risk in the entire world is increasing and is clearly concentrated in poorer countries with weaker governance.

Registered high-intensity disasters directly affected the operations of health systems, damaging health services' facilities, causing unexpected deaths rates and a large number of wounded people in the affected areas. These events exceeded the response capacity of health facilities and interrupted basic services that are essential for these health facilities' operations.

Likewise, they affect indirectly the operations of the health systems, as they lead to huge population displacements from the affected zones towards areas where health services cannot cope with the attention for this displaced population. At the same time, the risk of potential disease transmission is increased and there are food shortages that may affect the appropriate food intake.

Changes in legal frameworks, as seen in the reforms of National Laws, are the fundamental basis for the entire institutional change process these countries are going through in terms of disaster risk management, as these countries increase their commitments in the issue.

However, these changes are not isolated from the international context, as they reflect action proposals that were set in the Yokohama Action Plan (1994), and in the new "Hyogo Framework for Action 2005-2015: building the resilience of

nations and communities to disasters”, which is the product of Hyogo’s World Disaster Reduction Conference (Japan, 2005) and the Millennium Declaration.

As natural disasters are a condition of permanent danger in the region’s countries, counting on limited resources to face them, it is necessary to tackle the problem in an integral way with all the UNASUR countries.

## **THE EVOLUTION OF EMERGENCY AND DISASTER RESPONSE AND OF DISASTER RISK MANAGEMENT**

Countries have always been exposed to and faced either natural or man-made emergencies or disasters. In general, we can say all places on earth have been affected one way or another by some kind of natural disaster.

Due to the huge number of victims these disasters produce, which have left images impregnated with grief and hopelessness lingering in our memories, we have made efforts to face these emergency situations throughout the years.

For decades, the organization of actions has focused in the response to these emergencies and disasters, as established in the framework of a traditional cyclical sequence of disasters.

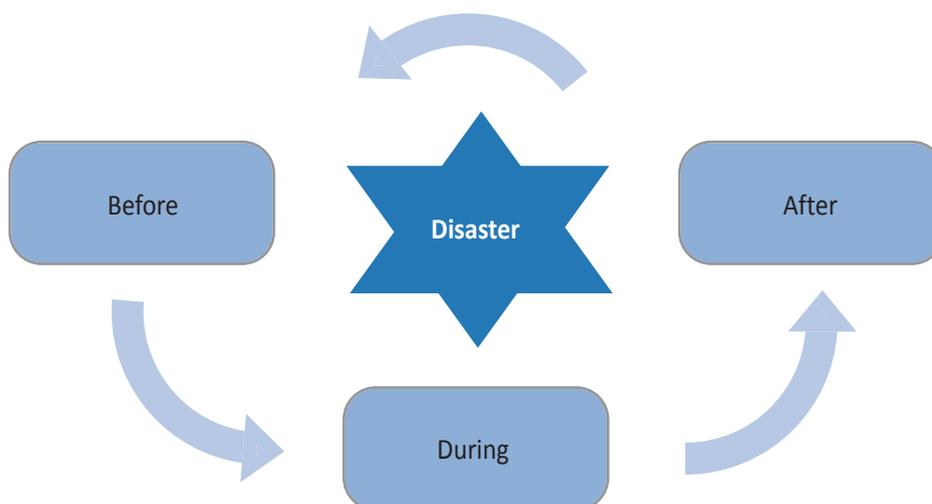
The “cycle of disasters”, as this system of organization is called, related three (3) phases and seven (7) steps, in which the disasters’ behaviour and management were classified.

This system of organization based the way it acted on the event or disaster and on its impact. This means it based its actions in previous activities or “before the disaster” with the objective of avoiding bigger damages in the disaster’s impact, minimizing its impact, structuring response and formally declaring the imminent occurrence of the event, so as to carry out all the response activities either “during the disaster”, or in the emergency period, or right after the event. At the same time, it comprehended activities “after the disaster”, like recovering the affected zone, rehabilitation and reconstruction.

Thus, we present the case of Peru, as the 43<sup>rd</sup> anniversary of the fatidic Sunday May 31st comes close, when the departments of Ancash, Huánuco, La Libertad y Lima were affected by an earthquake measuring 7.8 on the Richter scale. It had the epicentre on the shores of Casma and Chimbote, in the Pacific Ocean.

The number of estimated deaths was around 80,000 and approximately 20,000 people disappeared. The hospitalized wounded amounted to 143,331 and the losses of homes ranged from 80 to 90%. Around 3 million people were affected, and they were mostly left homeless or lost their families. One of the most affected zones was the Callejón de Huaylas, where most of the villages were destroyed at a 97% rate. Two of them were completely shattered by a landslide caused by the earthquake.

Figure 1 – Disaster's cycle



Source: Elaborated by the authors.

As a result, the Mobile Field Hospital of the Peruvian Institute of Social Security was established by Dr Donald Morote on 3<sup>rd</sup> of July 1970, as an immediate response to aid the injured by the Huaraz earthquake. Twenty-two doctors, 10 nurses and 15 nursing technicians joined as volunteers<sup>1</sup>.

After that, Decree 19338 of March 28<sup>th</sup> 1972 created the National System of Civil Defence (SINADECI) as a part of National Defence. It aimed to protect the population and prevent damages, whilst providing timely and appropriate aid and ensuring rehabilitation in case of disasters or calamities of every size, despite of the origin.

History also has references of this issue in the case of Colombia, where the first occurrence of legislation on aid organisms for victims of disasters dating back to 1875. The Government created the National Aid Commission to provide attention and channel aids because of the earthquake that destroyed Villa del Rosario de Cúcuta on May 18<sup>th</sup> 1875.

Then, the additional actions the Government took were reactive. In September of that year, Santander State Assembly, which gathered at El Socorro, promulgated a law that fostered the reconstruction of the city. One of the articles stated: “The new city of San José de Cúcuta will be built in the site previously occupied by this population, taking into consideration the same location of parks and public buildings, if possible”<sup>2</sup>.

We may note that, then, the regulations didn't consider the prevention of new risks for the reconstruction phase of new buildings, which leads us to the

consideration that keeping the infrastructure that identifies a population of a community has a big impact in a country's economy and development.

Afterwards, Law 49 of September 22<sup>nd</sup> 1948 created the National Aid in case of Public Calamity, as a consequence of the facts of April 9<sup>th</sup> 1948, in an agreement between the National Society of Colombia's Red Cross and the Ministries of War and Hygiene<sup>3</sup>.

Social emergency situations have determined the creation of a national organism, being the first occurrence the Legislative Decree 3398 of 1965. Its 6<sup>th</sup> article states "*Civil Defence is part of the National Defence comprehending the group of measures, provisions and non-aggressive instructions aimed at avoiding, outweighing or diminishing the effects of enemy's or nature's actions may incur on the social conglomerate's lives, moral and assets*".

*"The aforementioned reveals what we said on acting but reactively upon disasters, and this situation was similar in many countries"*, and this generated a huge concern in the international community, which understood the increasing magnitude, recurrence and the number of affected people of natural disasters. These considerations induced the United Nations to launch the International Decade of the Reduction of Natural Disasters 1990-1999 aimed at raising awareness on the importance of reducing disasters. The acquired experience during this decade boosted a conceptual change, coming from a simple response to disasters to the reduction of disasters.

In 1993, the Chilean Health Ministry's Department of Emergency and Catastrophic Issues saw an opportunity in the International Hospital Architecture and Engineering Seminars and introduced the subject "Natural Disasters from a planning perspective for the specific case of hospitals".

Meanwhile, Ecuador developed seminars on the effect of disasters on health infrastructure in 1993 and 1994. These meetings raised local authorities' awareness, which fostered the implementation of other projects.

Also in the beginning of the 1990's, Venezuela had already carried out preliminary studies on hospital vulnerability, which evidenced main deficiencies in non-structural aspects due to the lack of preventive maintenance programmes for the facilities.

In the meantime Colombia, in 1993, gathered representatives of the institutions and sectors linked to health infrastructure with the goal of formulating an integral project for researching and reducing vulnerability in the country's strategic hospitals. After this initiative, with the commitment of a National Calamity Fund, activities in one strategic hospital were initiated.

These initiatives were complemented with the development of a project previously financed by the European Commission Humanitarian Aid Office (ECHO) for the Vulnerability Analysis and preparations for facing disasters in four Andean countries: Chile, Ecuador, Venezuela and Colombia.

The objective of the PAHO/ECHO project was to contribute for the evaluated hospitals so they could acknowledge and reduce their vulnerabilities in a manner they were not themselves a cause of human and material losses during a catastrophe. At the same time, their healthcare operations could be maintained.

In 1996, the International Conference on Disaster Mitigation in Health Facilities was convened by the Pan-American Health Organization under the auspices of the Mexican Government and with the support of DIRDN's Secretariat. In the occasion, recommendations on disaster mitigation in health facilities were adopted, whilst Latin American and Caribbean countries were urged to take the responsibility of protecting their own population and infrastructure from the impacts of natural disasters. They were also urged to declare the adoption of concrete measures to mitigate the impact of natural phenomena over health facilities as a health social, economic and political priority<sup>4</sup>.

The Peruvian Ministry of Health, alongside with PAHO, initiated a gradual process related to the disaster mitigation issue, where a self-funded project called "Mitigation of Hospital Vulnerability" was implemented. In 1997, the Ministry of Health included for the first time hospital mitigation in its budget, which enabled studies of seismic vulnerability in 13 hospitals around Peru, taking their physical and organizational aspects in consideration. Professionals of Engineering University's Centre for the Research of Earthquakes and Disaster Mitigation took part on the studies. This initiative was considered a novelty during the development of projects in neighbouring countries, since, differently from the PAHO/ECHO project, the Peruvian project counted solely on national funds from the Ministry of Health's Office of National Defence.

Later on, in 2000, the International Strategy of Disaster Reduction was adopted. This strategy promotes an international effort in disaster risk reduction and supports the implementation of the "Hyogo Framework for Action 2005-2015: building the resilience of nations and communities to disasters", which is the product of Hyogo's World Disaster Reduction Conference (Japan, 2005), not to mention the Millennium Declaration.

The Hyogo Framework is based on and seeks to accomplish the Millennium Goals, specifically on the 3<sup>rd</sup> Chapter on Priority Actions, where it is stated that:

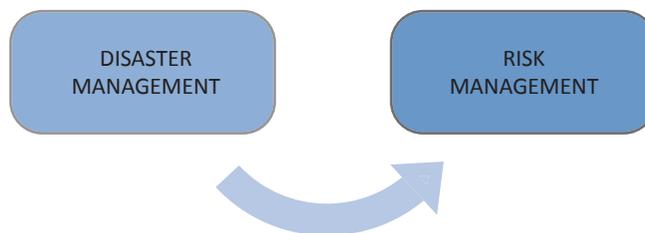
*"Disaster risk reduction is a cross-cutting issue in the context of sustainable development and therefore an important element for the achievement of internationally agreed development goals, including those contained in the Millennium Declaration"*<sup>5</sup>

Risk reduction has become a priority issue in the global agenda, since in the last few years, not only in the region, phenomena such as earthquakes and floods have

seriously impacted the countries, both socially and economically. And, endemic poverty is the structure that supports this vulnerability to great magnitude disasters.

The increase in massive emergencies and disasters, the loss of human lives, the delays in the affected countries' development and its economic fallouts have enabled the conceptual change from the "Disaster Management to the Risk Management".

Figure 2 - Conceptual Change



Source: Elaborated by the authors.

In this context, the region's countries have been incorporating progressively the new conceptual approaches into their national legislations. In the case of Peru, in December 2010, the National Agreement approved the incorporation of Disaster Risk Management as the 32<sup>nd</sup> State Policy, aimed at protecting the life, health and integrity of people, as well as the public and private assets; promoting and ensuring the population's placement and their equipment in safer zones; reducing vulnerabilities with equity and inclusion, and with an approach that comprehends risk estimation and reduction, response to emergencies and disasters, and reconstruction.

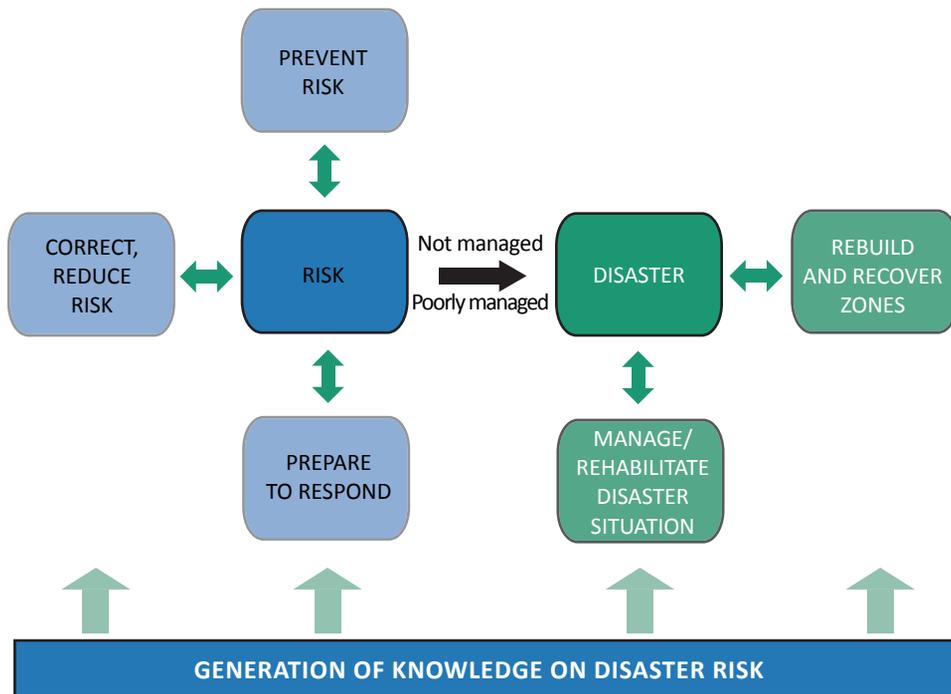
In February 2011, the Peruvian Government created, through Law 29644, the National System of Disaster Risk Management, which was regulated in May 2011, establishing: 1) the National Policy of Disaster Risk Management; 2) the Components of Disaster Risk Management; and 3) Processes of the Disaster Risk Management.

In Colombia in 2012, Law 1523 adopted the National Policy on Disaster Risk Management and established the National System of Disaster Risk Management.

This is understood as a social process oriented towards the formulation, execution, follow-up and assessment of policies, strategies, plans, programmes, regulations, tools, measures and permanent actions for the knowledge and risk reduction, as well as disaster management. The explicit goal is to contribute to the people's security, welfare and life quality, and to sustainable development.

Therefore, risk management is an essential development policy to ensure sustainability, territorial safety, collective rights and interests, improve the life quality of populations and communities at risk, which means it is closely associated with planning a safe development, with sustainable territorial environmental management in all levels of government, and with the population's effective participation.

Figure 3 – Disaster Risk Management



Source: Elaborated by the authors.

## HEALTH AND DISASTERS

Health facilities have a very important role during the disasters. Nevertheless, history has shown how vulnerable they are in these situations, according to summary chart of emergencies and disasters that took place in the member countries of UNASUR.

The loss of functionality of health facilities in disaster situations cause<sup>6</sup>:

1. Over 45 million people without healthcare
2. Direct losses of over 4 billion Dollars
3. Around 200 thousand people without emergency healthcare in hospitals

Chart 1 – Emergencies and disasters in the member countries of UNASUR

YEAR	COUNTRY	EVENT	DAMAGE
1835	Chile - Concepción	Earthquake	5.000 deaths
1906	Colombia	Earthquake	1.000 deaths
1906	Chile - Valparaíso	Earthquake	20.000 deaths
1939	Chile - Santiago	Earthquake	30.000 deaths
1960	Chile - Valdivia	Earthquake	5.700 deaths
1970	Peru - Ancash	Earthquake and flood	70.000 deaths
1983	Colombia -Popayán	Earthquake	Damages and services interruption in the University Hospital of San José
1985	Colombia	Volcano	25.000 deaths
1985	Argentina - Mendoza	Earthquake	10 facilities affected; 2 demolished and 1 displaces. 3350 beds
1985	Colombia	Eruption of Nevado del Ruiz	23.000 deaths
1987	Ecuador - Napo	Earthquake	Structural and non-structural damages in the General Hospital General Velasco Ibarra with 120 beds
1998	Ecuador - Manabi Province	Earthquake	Damages in the Basic Hospital Miguel H. Alcívar
1999	Venezuela	Floods	20.000 deaths
2007	Peru	Earthquake	540 deaths
2010	Chile	Earthquake	708 deaths, 6 collapsed hospitals. The most affected was Hospital Felix Bulnes, with over 400 beds
2010	Cusco	Floods	08 deaths and thousands of damages, destruction of roads and several affected crops
2011	Brazil - Teresópolis	Floods	55 municipalities in emergency situation, over 1000 deaths. 25 thousand families lost their homes

Source: Proposal for the conformation of the Network of Disaster Risk Management of UNASUR Health, 2011.

## EPIDEMIOLOGICAL SURVEILLANCE AND DISASTER RISK MANAGEMENT

One of Public health surveillance's key elements is epidemiology. Epidemiology is the study on the distribution of diseases on the populations, of other adverse events for health and its determinants.

Loayza mentions that public health surveillance is a practice based in the observation and day-to-day analysis of both the occurrence and distribution of diseases, and the factors leading to diseases for the effective and timely decision-making on necessary prevention and control measures.

Epidemiological Surveillance in disaster situations is aimed at giving precise and timely information on the health situation of the affected populations. However, methodological problems may arise when the relation accuracy and opportunity in the evaluation exceeds other requirements for the collection and analysis of data.<sup>7</sup>

The national surveillance systems in each country have tools, conditions and resources for obtaining information that enables monitoring the state and the trends of health – disease situations from which policies, strategies and activities can be elaborated and implemented.

In the case of Peru, the Ministry of Health's General Office of Epidemiology incorporated Directive OGE 001-2002 "Epidemiological Surveillance after Natural Disasters and Other Health Emergencies". Its goal is to reduce disease or death risk of the population in consequence of disasters or sanitary emergencies. It determines the healthcare request's epidemiological pattern after the events and timely detects the appearance of epidemic outbreaks, which enables the orientation of an adequate individual and collective healthcare.

Later on, in 2004, it elaborated the Manual of Epidemiological Surveillance in Disasters, which established the following lines of intervention:

1. Evaluation of the epidemic potential risk
2. Implementation of the surveillance system after sanitary emergencies
3. Implementation of Situation Room in disasters

In 2006, the Peruvian Health Ministry, through Ministerial Resolution 1019-2006, incorporates NTS 053-MINSA/DGE - V. 01, Health Technical Rule "Epidemiological Surveillance after (natural and anthropic) disasters and other Sanitary Emergencies". Its goal is to activate the System of Epidemiological Surveillance after the disasters and other sanitary emergencies so as to reduce the risk of dying or falling ill as a consequence of the effects of disasters and sanitary emergencies.

The system of epidemiological surveillance in disasters is conceived as a process that provides continuous information for decision-making in each of the stages in the disaster cycle, as follows:

**Preparation stage:** The health situation analysis provides a group of tools that, in an organized way, allows understanding of the health situation, understanding the health profile and prioritizing problems, recognizing the most vulnerable groups of the population and the zones with greater risk, and how these could be affected by the impact of disasters.

**Immediate response stage:** Fast epidemiological evaluation and determination of the potential epidemic risk caused by the disaster.

**Rehabilitation and reconstruction stage:** Epidemiological surveillance after disasters, situation room in disasters, analysis and information presentation.

According to this logic, the Chilean Ministry of Health published in December 2010 the Guidelines of Epidemiological Surveillance in Emergencies and Disasters.

Epidemiological surveillance has an important role not only in the process of response on disasters, but also because its inputs are valuable in the planning for the formulation of risk scenarios enabling to identify possible damages and, therefore, diminish the effects in the population's health.

As an evidence of facts previously described, there is the National Contingency Plan for the "El Niño" Phenomenon 1997-1998. It was elaborated considering epidemiological information, where risk scenarios were set up according to geographic and demographic characteristics, services infrastructure, human resources, input supply and social actors, and others. From this analysis, the following scenarios were established:

#### **Scenario "A":**

Regions and sub-regions of the Northern Coast: Tumbes, Piura, Lambayeque, La Libertad, Ancash, including Lima, where there would be rains and floods affecting water supplies and sewage systems, as well as transport lines. In this scenario, an increase in cases of malaria, dengue, acute diarrheal diseases (including cholera), pest, dermatitis, conjunctivitis and leptospirosis is foreseen.

#### **Scenario "B":**

Departments of the Southern Coast: Arequipa, Moquegua and Tacna; and of the Southern Mountains: Huancavelica, Ayacucho, Apurimac, Cusco and Puno, where temperatures would tend to decrease followed by droughts. These conditions would lead to an increase in acute respiratory diseases and pneumonia, food shortages and in an increase in the risk of dysenteric diarrheas.

#### **Scenario "C":**

Tropical forest zone: departments of Amazonas, San Martín y Ucayali, where a decrease in the temperature is expected, increasing the risk of acute respiratory diseases.

This document served as a reference for the elaboration of contingency plans of different sectors and other latitudes.

This is what is expected from the participation of epidemiological surveillance in the disasters cycle, respecting and developing activities in the three stages of the disaster. However, we note that the biggest contribution of epidemiological

surveillance is the research and collection of information after the disaster, which coincides with the cyclic organization system oriented to disaster management.

New trends in the Disaster Risk Management approach prioritize risk management before damage management, in a way epidemiological surveillance should be considered a continuous action providing information to different processes of Disaster Risk Management to prevent and reduce risk, as well as to prepare and respond to disasters. Its actions should go on with rehabilitation and reconstruction.

## DISASTER RISK MANAGEMENT IN INTEGRATION SPACES

The situations aforementioned present a better organization where the health sector lies, which are evidenced by the resolute efforts in different integration spaces, aimed at approaching the issue integrally.

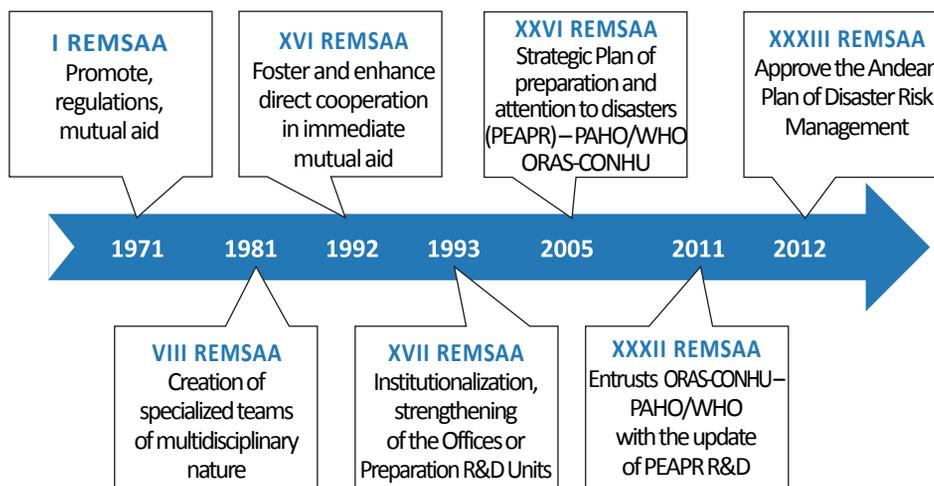
Although there are global initiatives, these aren't still materialized regionally. However, different integration spaces present advances, as follows:

### Advances in the framework of the Andean Sub-Region

This integration space has the Andean Health Organism - Hipólito Unanue Covenant (ORAS CONHU), which belongs to the Andean Integration System. Its objectives include the coordination and support to the member countries' efforts, individually or collectively, so as to improve their populations' health.

On this important integration space, we must highlight the Andean Health Ministers' concern on the devastating consequences and/or effects of emergencies and disasters, as can be seen in the following timeline.

Figure 4 - REMSAA Timeline



Source: Elaborated by the authors.



Thus, the first resolution from 1971, which referred to the collaboration among countries in disaster situation, has been elaborated as a response to the damages resulting from Yungay Earthquake - Ancash, Peru, right after it happened.

It is important to point out that the Andean Health Ministers demonstrates permanent concern on emergency and disaster situations, which is why submitted resolutions in different Meetings of Andean Health Ministers (REMSAA) were committed to:

1. Approve the Andean Plan for Disaster in Health Risk Management 2013-2017 (Andean Plan for Disaster in Health Risk Management 2013-2017. Bogotá - 2012) (REMSAA Resolution XXXIII/476)
2. Establish the Technical Commission for Emergencies and Disasters, which will be integrated by organisms in charge of the Disaster Risk Management or its equivalents within the Health Ministries; and charge them with the implementation of the Andean Plan (Andean Plan for Disaster in Health Risk Management 2013-2017. Bogotá - 2012)
3. Charge the Executive Secretariat of ORAS-CONHU with the follow-up and coordination of the Andean Plan's execution, with the support of PAHO/WHO (Andean Plan for Disaster in Health Risk Management 2013-2017. Bogotá - 2012)
4. Charge ORAS-CONHU with the formulation of coordination mechanisms, alongside with PAHO/WHO, so as to speed up the response to emergencies or disasters, especially in the Andean countries' borders. (Prevention to Emergencies and Disaster. Santiago, 2011) (REMSAA Resolution XXXII/472)
5. Request PAHO/WHO to revise and update, alongside with the countries, the Andean Strategic Plan of Preparations and Response of the Health Sector to Emergencies and Disasters for 2011-2015, in coordination with ORAS-CONHU. (Prevention to Emergencies and Disaster. Santiago, 2011)
6. Express the satisfaction for the work advanced by the theme groups of the member countries' Health Ministries, with the technical support of PAHO/WHO and coordination of ORAS-CONHU. (Prevention to Emergencies and Disaster. Santiago, 2011) (REMSAA Resolution XXVI/400).
7. Fully take on the Strategic Plan of Preparations and Attention to Disasters for granted, which is part of the present resolution. (Andean Strategic Plan of Preparations and Attention to Disasters. Santiago, 2005)
8. Adopt the motto "Safe Hospitals in the Face of Disasters" as a sectoral Andean policy aimed at risk reduction; decide that all new hospitals and health facilities be built with a level of protection that guarantees its optimal capacity in order to keep operating in disaster situations; and establish joint mechanisms that enables the implementation of proper mitigation measures of risk reduction in the existing health facilities. (Andean Strategic Plan of Preparations and Attention to Disasters. Santiago, 2005)<sup>8</sup>
9. Strengthen the Primary and Secondary Care Networks and the Epidemiological Networks for Disaster Prevention and Mitigation. (Andean Strategic Plan of Preparations and Attention to Disasters. Santiago, 2005)<sup>9</sup>

10. Request the Pan-American Health Organization (PAHO/WHO) and the International Federation of Red Cross, continue the technical cooperation in the sub-region so as to back the countries in the implementation of Strategic Plan of Preparations and Attention to Disasters. (Andean Strategic Plan of Preparations and Attention to Disasters. Santiago, 2005)<sup>10</sup>
11. Request the Executive Secretariat of the Andean Health Organism - Hipólito Unanue Covenant (ORAS CONHU) to manage the presentation of the Strategic Plan of Preparations and Attention to Disasters of the health sector to CAPRADE, as well as its incorporation and articulation with the Andean Strategic Plan of Preparations and Attention to Disasters (Andean Strategic Plan of Preparations and Attention to Disasters. Santiago, 2005)<sup>11</sup>
12. Recommend the Governments to institutionalize and strengthen the Offices of Preparation Units for Emergency and Disaster Situations of each of the countries' Health Ministries at an adequate level, directly depending on higher management. It must include the technical, administrative and budgetary attributions and development, in order to enable the accomplishment of its specific task. (Health preparations for Disaster Situations, Cuenca, 1993)<sup>12</sup> (REMSAA Resolution XVII/305).
13. Recommend the Executive Secretariat to promote the meeting of those responsible for the Priority Area for Disasters and Attention to Emergencies with the participation of Disaster Coordinators of the Health Ministries (Health preparations for Disaster Situations, Cuenca, 1993)<sup>13</sup>
14. Recommend Governments to place greater emphasis in the attention to secondary disasters to human activity in the sub-region's countries. (Health preparations for Disaster Situations, Cuenca, 1993)<sup>14</sup>
15. Recommend the Executive Secretariat to boost formal agreements among the member countries in order to define bilateral or multilateral cooperation terms and facilitate the integration of regional activities in the Health Sector in Preparation for Emergencies and Disasters. (Health preparations for Disaster Situations, Cuenca, 1993)
16. Reinforce the preparation program for disasters and attention to emergency of the health priority area of cooperation among countries of the Andean Sub-region. (Health Preparations of Disaster Situations, Santa Cruz, 1992) (REMSAA Resolution XVI/283).
17. Strengthen Health Ministries' Offices of Preparation Units for Emergency and Disaster Situations (Health Preparations of Disaster Situations, Santa Cruz, 1992)
18. Promote the operation of National Intersectoral Committees on Emergencies and Disasters, constituted in accordance with UN's General Assembly's Resolution A/41/169 (Health Preparations of Disaster Situations, Santa Cruz, 1992)
19. Foster and increase direct cooperation of non-immediate mutual aid among frontier States, Departments or Municipalities, which share similar risks and vulnerabilities. (Health Preparations of Disaster Situations, Santa Cruz, 1992)

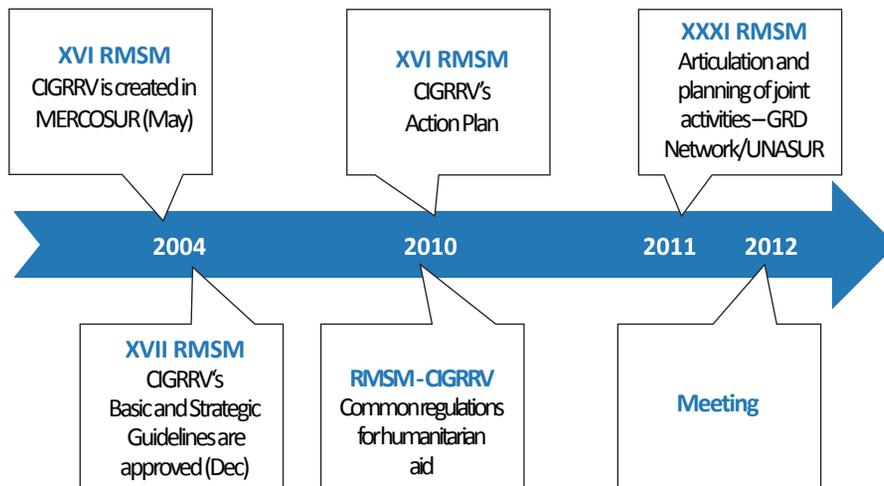


20. Request the Executive Secretariat to carry out necessary procedures to achieve International Technical Cooperation. (Health Preparations of Disaster Situations, Santa Cruz, 1992)
21. Give it top priority, according to modern reviews on damage caused by the mentioned disasters and to what it represents to the affected populations (Health Preparations of Disaster Situations, Caracas, 1981) (REMSAA Resolution VIII/138)
22. Increase research and analysis of existing experiences so as to appropriately plan the type, quality and amount of timely aid, with the objective of not creating misunderstandings in the affected countries and in the countries able to provide aid. (Health Preparations of Disaster Situations, Caracas, 1981)
23. Increase the creation of normative, multidisciplinary and high-level specialized teams within the public administration to coordinate the activities to be executed at a national level and with other countries. (Health Preparations of Disaster Situations, Caracas, 1981)
24. Empower the work teams in Health Ministries to coordinate all the action capacity to respond to emergencies. (Health Preparations of Disaster Situations, Caracas, 1981)
25. Unify information systems, team models and necessary regulations to facilitate the coordination with member countries.
26. Promote the adoption of permanent legislations for the prevention of emergency situations arising from catastrophes, so as to legally back the exception measures that may be needed, which must be included in a National Emergency Plan (Collaboration in Disaster Cases, Lima, 1971) (REMSAA Resolution I/7)
27. Take the necessary measures so the countries of the Andean area timely exchange information on their respective emergency plans in order to appropriately guide the collaboration that may turn out. (Collaboration in Disaster Cases, Lima, 1971)
28. A group of experts from countries of the Andean Area may study the valuable accumulated in this field, so as to facilitate the progressive improvement of the group of organizational and technical rules for regulating and enhance procedures of immediate aid, in the recovery stage and in the national-level planning of action for disasters. (Collaboration in Disaster Cases, Lima, 1971)
29. In case of a disaster, the superior national authorities must be the ones in charge of the communicating with the affect country's counterpart, offering human resources and aid materials so the recipient country is able to signal where and under what conditions it wishes to receive the aid. (Collaboration in Disaster Cases, Lima, 1971)
30. Establish coordination with international scientific organisms so these can channel their aid according to the emergency circumstances. (Collaboration in Disaster Cases, Lima, 1971)

## Advances in the framework of the Southern Common Market - MERCOSUR

The States that are part of the Southern Common Market - MERCOSUR (Republic of Argentina, Federative Republic of Brazil, Republic of Paraguay and Oriental Republic of Uruguay, according to the bloc's conformation until the first half of 2012) and Chile, as an Associate State, share a communion of values expressed in their democratic and plural societies, in their defence of fundamental liberties, human rights, environment and sustainable development, as well as in their commitment to the consolidation of democracy, legal certainty, struggle against poverty, and economic and social development with equality.

Figure 5 - CIGRRV Timeline



Source: Elaborated by the authors.

Activities towards strengthening response capacity in the countries in face of a disaster are also developed in this integration space.

1. In the 16<sup>th</sup> MERCOSUR Meeting - Meeting of Health Ministers, through Agreement 05/04, priority of the issue of adopting the new concept of risk management was ratified. The Intergovernmental Commission of Risk Management and Vulnerability Reduction (CIGRRV in spanish) was created in MERCOSUR, adopting the new intervention concept in situations of disaster to the full risk management.



2. In the 16<sup>th</sup> MERCOSUR Meeting – Meeting of Health Ministers, through Agreement 04/05, an Action Plan was approved as a result of the Basic and Strategic Guidelines and activity timetable of Intergovernmental Commission of Risk Management and Vulnerability Reduction of MERCOSUR and Associate States, proposing:
  - The elaboration of a Regional Policy on Risk Management and Vulnerability Reduction in MERCOSUR and Associate States
  - The development of a Regional Common Emergency Plan for the Health Sector in preparation and response to disaster in MERCOSUR and Associate States.

This initiative gathers every three years, when the countries have the opportunity to jointly define a highest-level hemispheric agenda that addresses urgent challenges and boosts a positive change.

### **Advances in the framework of the Americas**

During the 6<sup>th</sup> Summit, which took place in April 14<sup>th</sup> and 15<sup>th</sup> 2012, 34 Heads of State and Government approached the central topic of the meeting: “Connecting the Americas: Partners for Prosperity”. The following lines of action were developed: integration of the physical infrastructure and regional cooperation as means for achieving higher development levels and overcoming the hemisphere’s challenges; poverty, inequality and inequity; disaster risk reduction and management; access and use of information and communication technologies; citizen safety and transnational organized crime. In this Summit, Americas’ Heads of State and Government committed to:

1. Reaffirm disaster risk management is a priority of national public policies and their development strategies. (Disaster Risk Reduction and Management, Cartagena, 2012)
2. Prioritize resource allocation and the design of financial protection strategies, when needed, as means to mitigate the social, economic and environmental impact of disasters with the support of sub-regional, regional and international financial institutions, among others. (Disaster Risk Reduction and Management, Cartagena, 2012)
3. Strengthen our institutional platforms for disaster risk management, in collaboration with sub-regional and international mechanisms through mutual aid and solidarity-based cooperation strategies, as means to enable joint research, the exchange of knowledge, best practices and experiences learnt on the issue, and technology transfer under agreed terms. (Disaster Risk Reduction and Management, Cartagena, 2012)

4. Strengthen regional and sub-regional tools and existing initiatives on disaster risk reduction and management and on humanitarian aid; as well as coordination and cooperation mechanisms to create synergies, with emphasis on the importance of coordination. (Disaster Risk Reduction and Management, Cartagena, 2012)
5. Work with sub-regional, regional and international financial institutions in order to enhance financing mechanisms for the adaptation to climate changes, mitigation, recovery, rehabilitation and reconstruction, oriented to disaster risk reduction and management and to strengthening of communities' and nations' resilience, which are vulnerable or affected by disasters. (Disaster Risk Reduction and Management, Cartagena, 2012)
6. Designate, where necessary, and strengthen, where existing, national and institutional focal points to foster a more efficient coordination among Inter-American system organisms, international and regional organisms and sub-regional mechanisms, as well as to promote the use of virtual tools in this context, so as to speed up and enhance the efficacy of response on emergencies and catastrophes. (Disaster Risk Reduction and Management, Cartagena, 2012)

### **Advances in the framework of Union of South American Nations – UNASUR**

In the South American regional integration scenario, the South American Health Council (UNASUR-Health) proposes the “Consolidation of South America as an integration space for health and development”, integrating sub-regional efforts and achievements.

In this sense, UNASUR's Constitutive Treaty mentions the “protection of biodiversity, hydro resources and ecosystems, as well as cooperation in catastrophe prevention and in the struggle against the causes and effects of climate change”.

In 2010, the initiative to create a Network on Disaster Risk Management from a health perspective was set up aiming to merge all the efforts of different integration spaces, in which the member countries of UNASUR are also part.

The framework for the formation of the Network on Disaster Risk Management is described as follows:

1. In the 2<sup>nd</sup> Ordinary Meeting of the Coordinating Council of UNASUR, which took place on April 27<sup>th</sup> and 28<sup>th</sup> 2010 in the city of Cuenca, Ecuador, Peru and Chile committed to boost the formation of a structuring network on emergencies and disasters right after the presentation of the Post-Disasters Situation Report in Chile and the Situation Report in Haiti due to the earthquake that devastated it.



2. In the 2<sup>nd</sup> Meeting of Ministers of the South American Health Council, which took place on April 29<sup>th</sup> and 30<sup>th</sup> 2010, the Five-Year Plan 2010-2015 was approved. Due to the dynamism of the region's health problems, the ministers requested the Coordinating Committee and the Technical Groups to develop, among others, subjects the Emergencies and Disasters so as to incorporate them into the Five-Year Plan.
3. In the 2<sup>nd</sup> Meeting of South American Health Council's Technical Group on Development of Human Resources Management (GT RHUS), which took place in the city Lima, Peru, on November 18<sup>th</sup> and 19<sup>th</sup> 2010, the Entitled Coordinator of GT RHUS proposed the creation of the Network on Disaster Risk Management of the South American nations, in the framework of Structuring Networks. This proposal was backed by the Director of the Peruvian Health Ministry's General Office of National Civil Defence, in the terms established by the document "Conformation Proposal of UNASUR-Health's Network on Disaster Risk Management", which was approved unanimously by the Technical Group.
4. On March 3<sup>rd</sup> 2011, so as to conform the Network on Disaster Risk Management of the South American Nations, the Teleconference on Emergencies and Disasters was carried out with the participation of representatives of National and International Organisms and of Health Ministries of the member countries of the Union of South American Nations (UNASUR). Representatives of the Emergency and Disaster Offices of Argentina, Bolivia, Brazil, Colombia, Chile, Ecuador, Paraguay and Peru expressed their favourable opinions on the "Conformation Proposal of UNASUR-Health's Network on Disaster Risk Management".
5. In the Meeting of the Coordinating Committee in preparation for the 31<sup>st</sup> Meeting of Health Ministers of MERCOSUR, which took place in the city of Montevideo on December 5<sup>th</sup> and 6<sup>th</sup> 2011, the National Coordinators, due to the upcoming creation of the Disasters Network in the framework of UNASUR, requested the Intergovernmental Commission on Risk Management and Vulnerability Reduction (CIGRRV) to articulate and plan joint activities so as to optimize resources and lessons learnt. CIGRRV gathered on May 30<sup>th</sup> and 31<sup>st</sup> in Argentina to elaborate the proposal that must be incorporated in the Plan of UNASUR's Network of Disaster Risk Management.
6. In the 6<sup>th</sup> Meeting of the South American Health Council in the city of Asunción, Republic of Paraguay, in April 20<sup>th</sup> 2012, the "Network on Risk Management and Disaster Mitigation", through Resolution 04/2012, decides:
  - a) Establish a Network of Disaster Risk Management from a health perspective in the framework of UNASUR, which enables risk reduction and timely

and appropriate response in disaster situations through a mechanism of strengthening and capacity generation in the health systems.

- b) Elaborate a Work Plan within no more than 60 days and periodically inform the Pro Tempore Presidency on the status of the Plan.
  - c) Charge Peru's Health Ministry with the coordination of the Network alternately with Chile's Health Ministry, as well as with the elaboration of the Work Plan and presentation of periodic reports.
7. In the 7<sup>th</sup> Meeting of the South American Health Council, which took place in the city of Lima, Peru, on September 6<sup>th</sup> 2012, the Council approved the Work Plan of the Network of Disaster Risk Management, and took the responsibility to articulate the activities with the South American Defence Council (CDS) and the Council of Infrastructure and Planning (COSIPLAN).

### **Challenges of the Network on Disaster Risk Management of the Union of South American Nations – UNASUR Health**

- a) Consolidate the Network on Disaster Risk Management from a health perspective in the framework of UNASUR, as a health integration space incorporating the efforts and achievements of regional integration mechanisms so as to reduce risk, to timely and appropriately respond to disaster situations, and to promote common policies and coordinated activities among the member countries

The establishment of the Network on Disaster Risk Management will enable its acknowledgement as structuring institution of the health systems with the capacity to put in march and strengthen, in an effective and sustainable way, the health systems and services in emergency and/or disasters. This may be carried out mainly as a health authority and for the development of human resources, through high quality health personnel training activities for the South American health systems and through knowledge exchange, and collective activities for the creation of national capacity and solidarity in emergency and disaster situations.

- b) Organization of the Network on Disaster Risk Management – UNASUR, which will define its members' attributions and responsibilities, its organization and its relation with UNASUR organisms and other institutions.
- c) The Strategic Plan of Disaster Risk Management from a health perspective in the framework of UNASUR will be established as fundamental element in the implementation of the Network on Disaster Risk Management, considering the following Strategic Guidelines:

1. Regulate and strengthen disaster risk management at a regional level on a health perspective
2. Capacity strengthening and generation
3. Disaster risk reduction
4. Preparations and response
5. Mutual assistance and cooperation among countries
6. International cooperation

Finally, Disaster Risk Management is a new approach that is under implementation in the region's countries in a heterogeneous way, with the intention of reducing the impact of disasters in our populations. We understand that this regional integration process will contribute to this objective, as it will permit the processes' implementation and standardization, as well as to implement regional policies to reduce disaster risks and provide an appropriate response of mutual aid among our affected countries.

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## VIII. Epidemiological surveillance of non-communicable diseases

*Jonatan Konfino  
Daniel Ferrante*

### INTRODUCTION

**N**on-communicable diseases (NCDs) are the main threat to global health, as they account for 36 million deaths per year and are the leading cause of death in the entire world. Cardiovascular diseases, cancers, respiratory diseases and diabetes currently account for 60% of those at a global level, and for 80% in low- and medium-income countries. Moreover, the NCDs are also the leading cause of years of potential life lost, as well as being associated with a substantial burden of disease. A 17% increase is expected in the next 10 years<sup>1</sup>.

The development of the NCDs sees the repetition of multiple factors: environmental, genetic, demographic, socio-economic and cultural factors, among others. However, some risk factors are closely related to lifestyles and, therefore, are susceptible to being changed with healthy interventions. They explain over 80% of the NCDs: smoking, unhealthy diet, physical inactivity and alcohol abuse<sup>2</sup>.

In low- and medium-income countries, the burden of these diseases is very high, as a consequence of the increase in life expectancy and the decrease in fertility, which leads to an increase in morbidity and death rates by NCDs. In many cases, this scenario is still impacted by communicable diseases. The fact currently 80% of deaths by NCDs take place in medium- and low-income countries, especially in their poorest populations, is a signal of the need and obligation of controlling them because they represent one of the main reasons for health inequity.

According to the World Health Organization (WHO), 4.45 million people die per year because of NCDs in the Americas, 37% of which are younger than 70. It is estimated that more than 200 million inhabitants of this region have some NCD, and many more are at risk of developing one as a consequence of habits and risk behaviours, like tobacco consumption, passive exposure to smoke, unhealthy diet, physical inactivity, obesity and harmful use of alcohol<sup>3</sup>. These diseases are estimated

to cost around USD 500,000 per year for low- and medium-income countries, which account for 4% of their gross domestic products<sup>4</sup>.

In 2008, the World Health Organization elaborated and published the “2008-2013 Action plan for the global strategy for the prevention and control of non-communicable diseases”, which is a milestone in the struggle against NCDs<sup>2</sup>. This plan has the following goals: increase the priority to NCDs in the framework of development activities in the global and national levels; integrate prevention and control of these diseases in the policies of all levels of government; establish and strengthen national NCD’s policies and plans of prevention and control; promote alliances for the prevention and control of NCDs; and monitor (*surveillance*) the NCDs and their determinants, and assess the progresses in the national, regional and global levels.

On this last item and as means to develop cost-effective measures in the field of NCDs, it is necessary to count on appropriate, timely and organized information in a system that enables the design of timely policies, the continuous evaluation of progresses, the reallocation of resources and the monitoring of the implemented health policies<sup>5</sup>. The Centers for Disease Control and Prevention (CDC) has defined surveillance as a continuous recollection, analysis and systematic interpretation system for the planning, implementation and assessment of practices in public health in a timely manner. The last link of this chain is the application of data into disease prevention and control. This and other definitions demonstrate the importance of developing an adequate surveillance system to prevent and control NCDs.

In order to address the complexity and impact of NCDs, it is necessary to work on three lines of action: health promotion policies, adjust healthcare towards patients with chronic diseases and epidemiological surveillance of NCDs and their risk factors. The three issues will be approached further on, with special emphasis on the development of a surveillance system for NCDs.

## LEADING STRATEGIES OF HEALTH PROMOTION

Population-based health promotion strategies have higher impacts in the population’s welfare. Health promotion is based in three integral and complementary strategies, pointing to not only stimulating the individual to choose healthier options in this life, but also to consistently work on the environment so this healthier choice is more accessible. These three axes could be summarized in:

- Promotion of healthier lifestyles
- Promotion of regulations of products’ and services’ supply
- Promotion of healthy environments

The promotion of healthy lifestyles is aimed at influencing conducts at an individual level, and in many cases it is carried out through education, social communication and information to the customer, among others. Regulations of products' and services' supply are one of the main promotion actions when it comes to the effectiveness of its impact in the population. These regulations may be carried out through laws, like tobacco controls that bar sales for minors, tax tobacco, so it's less accessible because it's more expensive, forbid advertising, sponsorship and regulate the packing of cigarettes. In this sense, there are examples of laws regulating alcohol sales. Other than regulation through laws, there is also the regulation of supply through voluntary agreements that, once subscribed, are compulsory. One example of this is the strategy being carried out in Argentina to reduce the population's salt consumption, called "Less Salt, More Life"<sup>6</sup>. This initiative is based in voluntary agreements with the food industry so they reduce the amount of salt in foods; the percentage of the reduction varies according to the food. There was also an agreement with artisan bakers, so they make bread with less salt. This kind of strategy is an example of how to work on product's supply even though there are no laws regulating it. Finally, in relation with the last item, the promotion of healthy environments is the strategy's third axis means promoting smoking-free zones, environments conducive to physical activity, healthy environments in municipalities, schools, workplaces and others, like universities.

## **ADJUSTING HEALTH SYSTEMS TOWARDS HEALTHCARE TO PATIENTS WITH CHRONIC DISEASES**

Health systems are structured to provide efficient care to acutely ill patients. However, it is necessary to adjust the systems to provide more efficient and effective health care to patients with chronic diseases. In this sense, Wagner et al. proposed an approach based in the *support to self-care* (for example, through educational materials for patients and payments to professionals who are dedicated to the education of patients with diabetes); *design of systems of service delivery* (like information systems with named population, programmed journey, patient reference and counter-reference systems); *support to evidence-based decision-making* (for example, the development of clinical practice guidelines, training and reminders); *clinical information system* (like unified clinical record, results registry and achievement of therapeutic goals)<sup>7</sup>.

## NCDs' SURVEILLANCE SYSTEM

### Vision

A system of NCD's and risk factors' surveillance is aimed at providing information on NCDs and its determinants to decision-makers and other information users, enabling the design, evaluation and monitoring of actions for prevention and control.

### Purpose

The purpose of NCD's and risk factors' surveillance is to organize and consolidate surveillance and control of NCDs in the framework of a control strategy within national health ministries and at regional and local levels.

### Goals of a system of NCD's and risk factors' surveillance

1. Monitoring the main NCD's and its risk factors
2. Guarantee the use of surveillance in the decision-making process and evaluation for the prevention and control of NCDs at national and sub-national levels

### Principles

A system of NCD's and risk factors' surveillance should prioritize information collection on risk factors distribution and trends, a small number of which accounts for most of the NCD's morbidity and mortality. It should also collect information on morbidity and mortality to monitor the impact of such risk factors.

This information should be useful for decision-making, so the close collaboration between information users and the surveillance system is essential. The commitment of different actors in planning information processes enables to ensure the usefulness of generated data and avoid duplication of efforts.

### Information sources

There are multiple information sources feeding the surveillance system. Many of them may come from new researches (for example the implementation of a national survey on risk factors) designed specifically for NCDs (this kind of source is referred to as *primary*). They may also come from databases that were conceived for other ends (like administrative databases), which, however, provide important information on NCD surveillance (this kind of source is referred to as *secondary*),

Following the model proposed by Canada on "natural history of disease", we can identify different sources according to the moment of the disease we intend to study: the determinants, the pre-clinical stage, the clinical stage and the results<sup>8</sup> (Table 1).

Table 1 – Model of NCDs Surveillance based in the “natural history of disease”, examples

Determinants	Pre-clinical	Clinical	Results
<b>Individual and environmental risk factors:</b>	<b>Tracking:</b>	<b>Diagnosis:</b>	<b>Mortality:</b>
Genes Family diseases Conducts Socio-economic factors and access to services	PAP, Breast and HTA	Shape and time	Death by causes
<b>Risk Factors:</b>	<b>Risk reduction:</b>	<b>Treatment and procedures:</b>	<b>Morbidity:</b>
Tobacco Food	Stop smoking Programmes	Surgeries, practices	Complications, disability, life quality
<b>Environmental:</b>		<b>Use of services:</b>	
Occupational exposure		Outpatient care and hospitalisation	
<b>Socio-economic:</b>		<b>Use of drugs:</b>	
Housing, poverty Education, prices Legislation		Use of drugs, interactions and adverse reactions	
Data source			
Surveys Census Secondary Data	Administrative databases Programmes' data	Hospital Registry Hospital discharges Administrative databases	Vital statistics Disease registry

Source: Elaborated by the authors, adapted from Health Surveillance Coordination Division, Centre for Surveillance Coordination Population and Public Health Branch, Health Canada (2003)<sup>8</sup>

On the other hand, it is important to know the characteristics of each information source so as to optimize its use, to avoid effort duplication and to be efficient in information generation (Table 2).

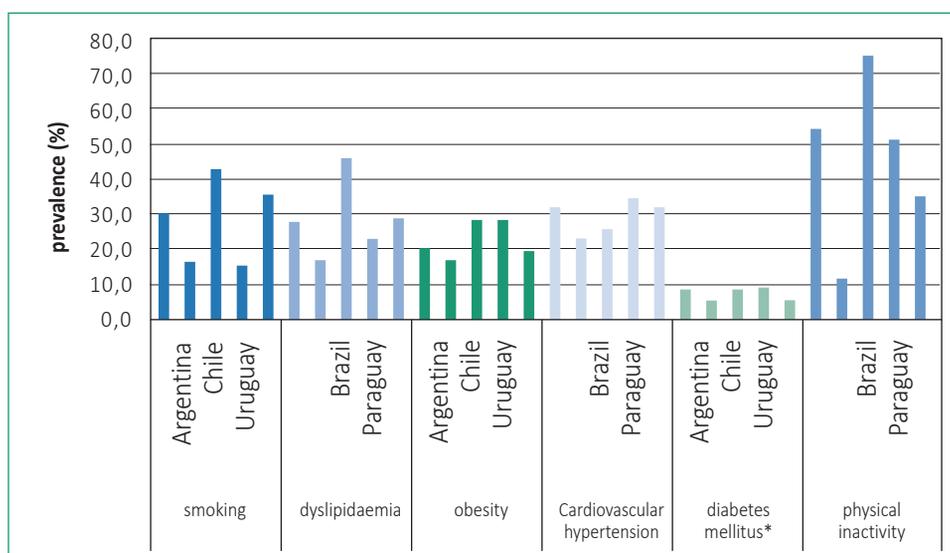
In the NCD surveillance strategies, monitor risk factors is a more cost-effective strategy since it enables to obtain information years before the occurrence of the disease, as well as to count of relevant inputs for the elaboration of timely promotion and prevention actions. National surveys of risk factors undoubtedly are key information sources for the surveillance of NCDs and risk factors. Currently, almost all countries in the region have population data of risk factors that enable the estimation of the population's epidemiological profile in relation with the NCDs (Graphic 1).

Table 2 – Data source for Non-Communicable Diseases Surveillance

Type of source	Information	Advantages	Disadvantages
Administrative data	Discharges, resource use, quality of care	Low cost, population, possible “record linkage”	Oriented to events, not people, availability, highly variable quality
Registry	Quality of care, Incidence, mortality	Detailed information, information on results	Cost, sustainability
Surveys	Risk factors, socio-economic aspects	Population data, specifically designed data collection	Not associated with events, not very useful if not periodical, cost and necessary resources
Vital statistics	Mortality	Usually complete, national coverage, trend evaluation	Incomplete registries, slack time, interpretation of subjacent cause vs. immediate cause of death

Source: Elaborated by the authors, adapted from Health Surveillance Coordination Division, Centre for Surveillance Coordination Population and Public Health Branch, Health Canada (2003)<sup>8</sup>

Graphic 1 – Prevalence of risk factors in adults (25-64 years) in the countries of MERCOSUR and the associate country (Chile) – 2011



Source: Elaborated by the authors out of the First Report on Surveillance of Non-Communicable Diseases of MERCOSUR, 2011<sup>9</sup>

\*Prevalence data on diabetes mellitus are on people over 18 years of age

For example, Argentina has carried out its first National Survey on Risk Factors (NSRF) in 2005, and has repeated it in 2009<sup>9</sup>. This second survey enabled the preliminary establishment of a temporal trend in the evolution of risk factors and brought about the possibility to evidence an increase in physical inactivity, obesity and diabetes, which compelled the authorities to develop concrete interventions to respond to these increases. Certainly, a further survey implementation will evaluate the results.

Some countries, like Brazil, are complementing the information obtained in the NSRF (that take place every 4 or 5 years) with data from telephone surveys on risk factors. Telephone surveys are usually carried out on a yearly basis and have some advantages if compared to population surveys, like NSFR: they are less expensive and simpler to implement, and they enable having information more frequently and including modules of other diseases or health problems. Some of their disadvantages are: they cannot be as extensive as NSFR, may not be as accurate (less still if compared with population surveys, which take objective measurements) and there may be biased responses related to the population that has access to landline telephones. This is because telephone surveys don't usually consider mobile phones because of the difficulties of obtaining patterns of these phones and of performing an over-15-minute-long survey through mobile phones (Chart 1). In this sense, Brazil has been successfully carrying out a phone survey called *Vigitel* for many years, in all state capitals<sup>10</sup>. Argentina carried out a pilot test in 2010 in the city of Buenos Aires with good results<sup>11</sup>, which permitted the incorporation of the phone surveillance strategy for risk factors (the way it is going to be implemented is still being evaluated).

This allows us to conclude that there is a way of developing risk factor surveillance that can be highlighted: continuous and periodical. The phone survey (like *Vigitel*) is an example of the former, whilst household surveys (like the 2005 and 2009 NSFR and in other countries) are a common way of carrying out periodical surveillance. Surveillance strategies that incorporate both systems are recommended. As the same time it is necessary to count on detailed information obtained through periodical household surveys, telephone surveys permit a more frequent and less expensive monitoring of the selected risk factor's trends.

Chart 1 – Characteristics of continuous (phone surveys) and periodical (household surveys) surveillance strategies

Surveillance	Telephone	Household
Costs x Survey	+	+++
Complexity	+	+++
Sustainability	++	+++
Periodicity	Continuous/annual	4 or 5 years
Survey's duration	Less than 15 minutes	40 minutes
Depth	Limited	Deeper
Opportunity	+++	+
Inclusion of modules	+++	+
Physical and chemical measurements	No	Possible

Source: Argentine Nation's Ministry of Health, 2011<sup>11</sup>.

Notwithstanding that, morbidity and mortality must also be part of the system, providing different and complementary data. On the other hand, data on social determinants of health, the environment, the legal framework (for example, legislations on smoke-free environments, Codex Alimentarius, etc.) and those coming from health services also complement the information scope that is necessary for better decision-making (Table 3).

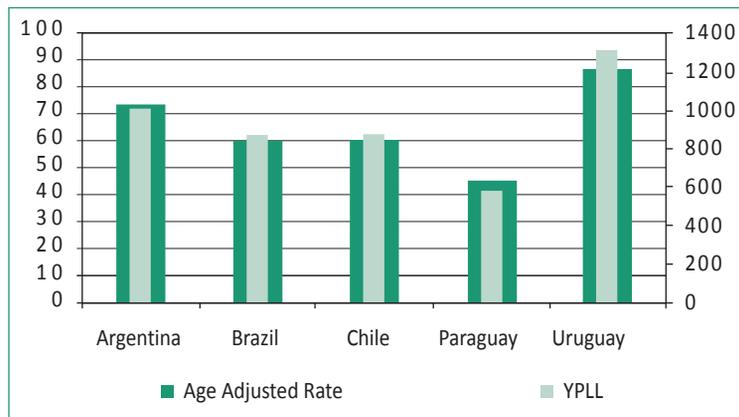
Table 3 – Surveillance Strategies for Non-Communicable Diseases

Surveillance Strategies			
Risk factors	Morbidity	Mortality	Health policies
<i>Adult population</i> <ul style="list-style-type: none"> <li>National surveys in risk factors</li> <li>Phone surveillance system</li> <li>Global survey on smoking</li> </ul>	<i>Population basis</i> <ul style="list-style-type: none"> <li>Cancer registry</li> <li>Cancer and cardiovascular diseases discharges and hospital registries</li> <li>Programme information</li> <li>Administrative data (use of services, drugs, procedures)</li> </ul>	Vital statistics (cardiovascular diseases (I00-I99), tumours (C00-D48), diabetes mellitus (E10-E14), chronic lung diseases (J40-J47))	Evaluation of laws (sanction, compliance) Evaluation of interventions
<i>Teenage population</i> <ul style="list-style-type: none"> <li>Global survey on smoking in teenagers</li> <li>Global survey on school health</li> </ul>			
<i>Administrative data</i> <ul style="list-style-type: none"> <li>National institutes of statistics</li> <li>Social security data</li> </ul>			

Source: Elaborated by the authors based on the Argentine Nation's Health Ministry, 2009<sup>12</sup>.

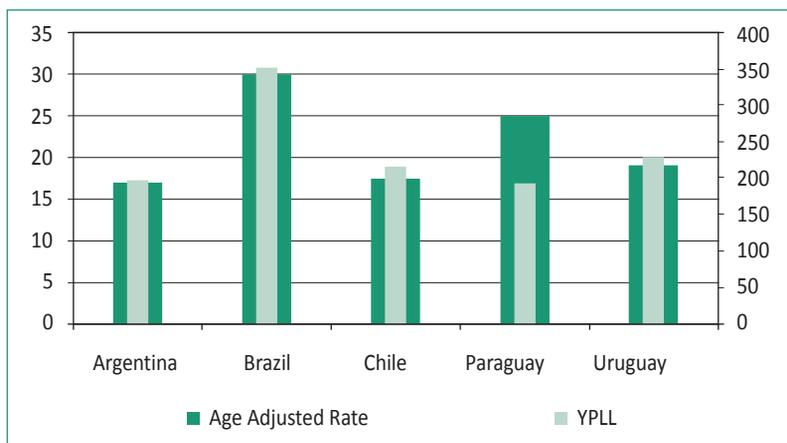
So as to surveillance on mortality and years of potential lost life (YPLL), for example, in the field of malignant tumours, Uruguay presents the highest figures amongst MERCOSUR and associated countries, followed by Argentina (Graphic 2). On the other hand, in terms of heart ischaemic diseases, Brazil presents the highest mortality and YPLL levels (Graphic 3).

Graphic 2 - Mortality (rates for 100 thousand inhabitants) and YPLL by malignant tumours in people under-70 in MERCOSUR and associate country (Chile)



Source: Elaborated by the Authors, based on the First Report on Surveillance of Non-Communicable Diseases of MERCOSUR, 2011<sup>13</sup>.

Graphic 3 - Mortality (rates of 100 thousand inhabitants) and YPLL for heart ischaemic diseases in people under-70 in MERCOSUL and associate country (Chile)



Source: Elaborated by the Authors, based on the First Report on Surveillance of Non-Communicable Diseases of MERCOSUR, 2011<sup>13</sup>.



The evaluation of policies or health interventions, specifically on NCDs, must be part of its surveillance. This evaluation should be considered from the very conception of the intervention and, therefore, the CDC Framework proposes six steps for programme evaluation<sup>14</sup>:

- Identify involved actors
- Describe the programme or intervention: definition, goals (they must be S-M-A-R-T, specific, measurable, attainable, relevant, and time-based), activities, products, resources and the context
- Evaluation: it must prioritize the programme's objective, evaluate designs, available resources, revise information sources and analyse the moment the analysis is being carried out (for example, probably the same strategy is not used to analyse a tobacco law before its sanction and after its sanction, once implemented)
- Collect credible information: there is a direct relation between credibility (and solidity) of data and the results' usefulness and utilization. This information must be useful, credible and timely for decision-makers. Finally, precision should be balanced with its implementation feasibility
- Analyse and interpret findings: elaboration of reports and summaries
- Ensure its use: getting this information to pertinent recipients, adjusting its contents and formats to different audiences.

For example, implementation evaluations have been carried out in Argentina, concerning local tobacco control laws. In the province of Santa Fe, a study was performed before and after the implementation of the law, in which the frequency of admissions for acute coronary syndromes was analysed. A decrease was observed right after the intervention<sup>15</sup>. This kind of evidence strongly backed decision-makers that hadn't implemented the laws and empowered local authorities against the constant attacks of the tobacco industry. On the other hand, the way 15 cities of the country were implementing tobacco laws was analysed, and some of them were 100% tobacco-free whilst others weren't. A substantial non-compliance was observed in both, but the 100% tobacco-free cities were more successful. This led to the conclusion that the enacting a law isn't enough for ensuring its compliance, which evidenced the need to strengthen the implementation of laws<sup>17</sup>. A similar example was observed in Uruguay.

The two previous cases are examples of how a research can be concrete, time-based, with a specific methodology analysing a specific problem in detail, but also how it can complement a surveillance system. This complementation forces us to consider carrying out researches to evaluate different interventions.

## Information use and dissemination

Surveillance systems shouldn't only recompile **data** in a systematic way, but also contextualize it in order to generate **information**. This information must be interpreted and oriented for a recommendation, constituting a **message**.

Communication has different elements that must be considered when disseminating results: emitter, message, receptor, channels, impact and evaluation<sup>16</sup>. Consequently, we must think before issuing a message what we want to say, to whom we want to speak to, through which media or product, with what language and which effects are desired. This analysis enables us to conclude on if we must elaborate a technical report, a press release, an executive summary, a scientific article, a report or all of them, in order the disseminate our results<sup>18</sup>.

## CONCLUSION

Struggling against the NCD epidemics poses a challenge to countries that must organise, strengthen and/or reorient their health systems. Fortunately, there is scientific evidence on the effectiveness of multiple interventions to improve health in this aspect, and its surveillance will enable the design of strategies, analyse and reorient systematically its implementation, focus its actions to vulnerable groups and evaluate its impact.

The effective communication of the findings is an essential component of a surveillance system. It is a basic item in all of the policies' stages. An emphasis on communication must have the same priority as information generation. Communication and the maximization of the use of information for decision-making are evidenced in the very definition of epidemiological surveillance, which means information for action<sup>19</sup>.

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**PART 2**  
**Health Surveillance as a  
space for South American  
Systems of Health's  
strengthening**





## IX. Innovating Experiences and Challenges for Health Surveillance

### INTRODUCTION

In this chapter we are going to present innovating experiences in the South American Health Surveillance sector. The priority themes were initially identified on ISAG's workshops on Health Surveillance and Sanitary Surveillance held in 2011. These experiences reflect the aspects considered to be the most important for the development of epidemiological surveillance, health and health environment strategies, to the experiences of countries suggesting solutions, both simple and innovative in order to face successfully the health threats and problems of the region.

To improve the understanding on the themes presented, innovative experiences should be structured in the following way:

1. Introduction putting into context of the theme
2. Main objectives
3. Methodology
4. Resources employed
5. Results
6. Experience evaluation

Thus, we expect it contributes for the appropriation of these experiences by other countries, with the necessary adaptations to their national realities.

## Innovative Experiences in Environmental and Epidemiological Surveillance

### Project “Malaria Control on Border Areas of the Andean Region: a community approach”(Pamafro)<sup>1</sup>

*Luis Beingolea More*

#### INTRODUCTION

The health staff of four Andean countries (Colombia, Ecuador, Peru and Venezuela) came together in 2002 before a high incidence of the disease on their borders, to prepare a project they called “Malaria Control on Border Areas of the Andean Region: a community approach”(Pamafro<sup>1</sup>).

This project contemplated a new strategy to approach the disease and its risk factors giving more emphasis on the social response coming from the organization and development of the organized community’s capacities. The objective group was constituted by native and multi-ethnic populations spread over a great extension of territory, with limited access to transportation systems, communications and a deficient system of healthcare<sup>2</sup>.

#### OBJECTIVES

##### General

- Diminish the incidence of malaria by 50% (prioritizing communities with incidence rates over 10%)
- Diminish global Malaria mortality by 70%
- Establish a system of diagnosis, sustainable communal treatment and control in the border region of the countries targeted.

##### Specific

- Promote and strengthen social and community organization, as well as their active participation in the planning and leadership in the fight against Malaria;
- Increase the access to malaria diagnosis and treatment for the target population;

- Design and implement a health information system (SIS) and a epidemiological surveillance system to homogeneous and integrated areas, so it unifies the existing ones in the Andean System of Epidemiological Surveillance and the National Health Informations Systems;
- To develop a voice and information communications network pilot project on the Peru-Ecuador border region;
- Develop essential researches with results to be applied on decision-making and interventions for the control and prevention of malaria on the homogeneous regions of the project.

## METHODOLOGY

The project started its activities on October 01st 2005 with the preparation and execution of studies of the baselines of the malaria situation and its risk factors on the homogeneous areas, understood as territories with similar geographic, environmental, demographic, social, and epidemiological characteristics, as well as healthcare access. The findings determined there was a big under-reporting of case notifications which doubled the ones reported by the formal epidemiological surveillance systems of the Health Ministry; that the multi-ethnic population didn't have the perception of diseases' risks neither of a way to prevent it; that malaria is unequally distributed in the territories it spreads, as it is concentrated in certain localities (NUTE5), districts or parishes (NUTE4); that the knowledge over the disease existed but preventive measures weren't usually carried out, which could be seen in malaria cases appearing in the same household or individuals, amongst other important conclusions.

In order to tackle the problem, the following lines of actions where established:

1. Community mobilization
2. Stratification for Malaria control, identifying 11 homogeneous areas between the countries borders in which 164 municipalities presented a >10 Annual Parasitic Index in which 1.292 were given priority.
3. Strengthening of the health system by training health agents, supply of diagnosis and treatment inputs; strengthening the distribution network, integrating with existing promoters, creation of a voice and data system, and strengthening of the epidemiological surveillance system: strengthening of diagnosis points and quality control;
4. Mobilization of resources and political commitment by improving the inter-relation of human resources, financing and technical support, as well as promoting the exchange of experiences amongst the countries, seizing the

emphasis in Malaria for the articulation of policies in health, support of technical staff and community, strengthening of political alignment internally and externally around the problem of malaria;

5. Strategic member's pact. Members of the supranational, national, regional and local spheres, such as UNICEF, PAHO, UNDP, UNAIDS, NGOs, local, municipal, regional governments, universities, research centers, public ministries and private companies.

## EMPLOYED RESOURCES

The proposal was presented to the Global Fund to Fight AIDS, Tuberculosis and Malaria for a total of US\$ 26.480.747 in five years of execution, delivered in two phases, the first assigned US\$ 15.906.747 and the second US\$ 10.574 dollars.

The project was evaluated and monitored through the Andean Coordinating Regional Plan, constituted in the framework of the donation contract signed under the Global Fund to Fight AIDS, Tuberculosis and Malaria and the Andean Health Organism – Hipólito Unanue Covenant, composed of Ministers of Health, by their representatives, as well as representatives of the civil communities of the Andean countries.

## RESULTS

### Impact objectives

- i. Morbidity: In 2005 (year the project started) Peru reported the higher number of malaria cases a total of 61% of the total presented that year (56.771/92.839), followed by Colombia 24% (22.472/92.839), Venezuela 8% (7.351/92.839) and Ecuador 7% (6.245/92.839). From September 2005 to (S.E. 38) 2010, a decrease in the number of cases was observed from 81% (92,753 to 17,194 cases). Ecuador has presented the highest fall in the number of cases, with 88% (771 cases), followed by Peru 84% (9,107 cases), Colombia 76 % (5,359 cases) and, finally, Venezuela 73% (1,957).
- ii. Mortality: The objective established for the context of the Project was to diminish the mortality by malaria by 70%. In terms of mortality by malaria, the number of deaths was 20 in the year of 2005, 18 in 2006, 13 in 2007, 11 in 2008, 8 in 2009 and two cases in 2010. It is important to highlight that when the gathering of the project's information was finished, no data from two countries was obtained. Nonetheless, both countries didn't have malaria deaths reported since 2005. Ecuador had one death case and there were no death during the project period in Venezuela.

- iii. The percentage of malaria cases by a parasite specie *Plasmodium falciparum* dropped by 82 % (from 29,293 cases to 5,192 cases) and by *P. vivax* in 81 % (from 62,351 to 11,914) from 2005 to September 2010 (SE 38).
- iv. Malaria Index; IPA 15.35 in 2005 to 2.7 in 2010, IVA 10.4 in 2005 to 1.8 in 2010 and IFA 4.9 in 2005 to 0.8 in 2010.
- v. Long-lasting Insecticide Mosquito nets were delivered to 650.000 people accounting for 20% of the homes in the intervention context with at least one mosquito net.
- vi. 2,885 community workers and 801 diagnosis microscope technicians were trained in malaria treatment. 493 microscopes were acquired and distributed for the strengthening of the diagnosis stations and treatment of malaria, the access to diagnosis inputs and anti-malaria medicines.
- vii. Strengthening of surveillance through focus on risk and communal education in personal health and community. Creation of four voice-information communication nets and computing and telecommunication groups.

## EXPERIENCE ASSESSMENT

- a. Health Ministries of four countries, the Health Andean organism, the Pamafro Project and the organized and represented society permitted the incorporation of a model of prevention and control of metaxenic diseases, in particular malaria, giving the community opportunity to take over directly their health protection through oriented measures to improve perception of the community over the disease and the way to prevent it;
- b. The malaria control strategies were adapted to the national realities, what has contributed to meet proposed goals;
- c. The education strategy with participatory focus allowed for the consolidation of measures of medium term social response. It has added through a strategy of community communication oriented towards the knowledge of citizen's rights and over the prevention measures and control of the disease, with emphasis on the health determinants related to malaria;
- d. The community work was emphasized to strengthen the organization, management, decision-making and presenting of initiatives for the prevention and control of malaria. Particular emphasis was placed on the local authorities motivation regarding the State and its responsibility in the creation of conditions to satisfy that right, as the inclusion of malaria in the public policies and the strengthening of alliances and inter-institutional coordination. The result aimed was no setbacks to the satisfaction of right to health (prevention and malaria control) because of juxtaposition of functions or objectives<sup>3</sup>.

## Experiences and Challenges in Surveillance and Control of malaria in Suriname<sup>II</sup>

*Marthelise Eersel*

### INTRODUCTION

Suriname has used malaria surveillance in a dynamic, continuous and systematic manner, as part of the programme designed for eliminating the transmission.

The malaria transmission is heterogenic, even when it takes place in a small country as Suriname, where transmission is allocated in one part of its territory.

### OBJECTIVES

The malaria surveillance in Suriname was part of the efforts to control the disease in order to maximize the impact of diagnosis and transmission treatment in each one of the different epidemiological layers.

### METHODOLOGY, EMPLOYED RESOURCES AND RESULTS

Due to the different ways of providing services in Suriname, surveillance also took different shapes.

There are three main malaria epidemiological situations as reference to different surveillance systems:

#### **A) Populations residing on the countryside consisting, primarily, of native and indigenous descendant people<sup>III</sup>**

The populations (approximately 50.000) live in tribes scattered along the countryside main rivers. Primary healthcare, including the services of malaria diagnosis and treatment, are provided by the NGO Medical Mission, which is financed by the government.

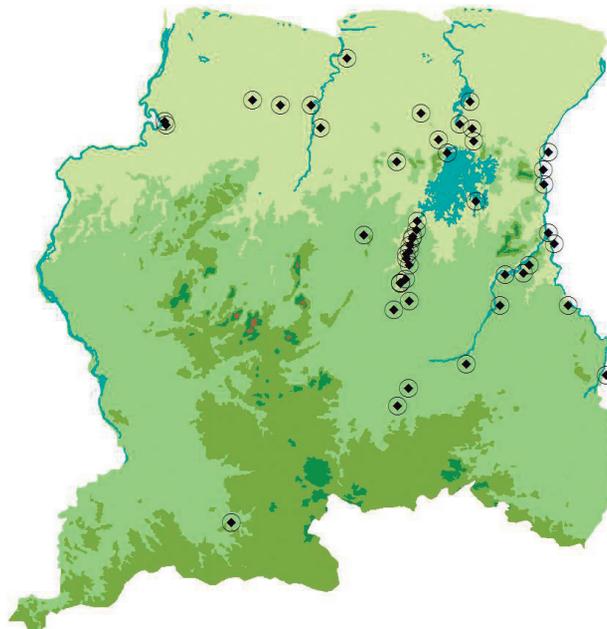
The Malaria surveillance system on this part of the countryside was developed through the existing system used by the Medical Mission based in priority communicable diseases, which were weekly reported by radio and, nowadays, by mobile phones or the Internet. Each week, health workers of the country's polyclinics informed the number of priority infectious diseases, amongst them malaria, to the Medical Mission in the capital, Paramaribo. All the malaria cases are confirmed by the clinic laboratory that presented reports. The numbers are immediately processed and an increase in the number cases initiates a chain

response in the base. To all confirmed cases in laboratory, be it by quick proof and/or by microscope in the local polyclinic, a blood smear is sent to the base for confirmation. All the confirmed malaria cases are registered by the polyclinic on an online list and are sent to the base for an analysis. These lists include the following variables: sex, age, type of *Plasmodium* and probable place where the disease was transmitted. Along the years, the system has improved with the formation and amplification of the microscope numbers and the training of the health workers.

Graphics 1 and 2 show the success of the malaria control program in the communities, especially amongst small children and women. The disease affects today mainly young men, who catch the disease in other places (such as gold mines).

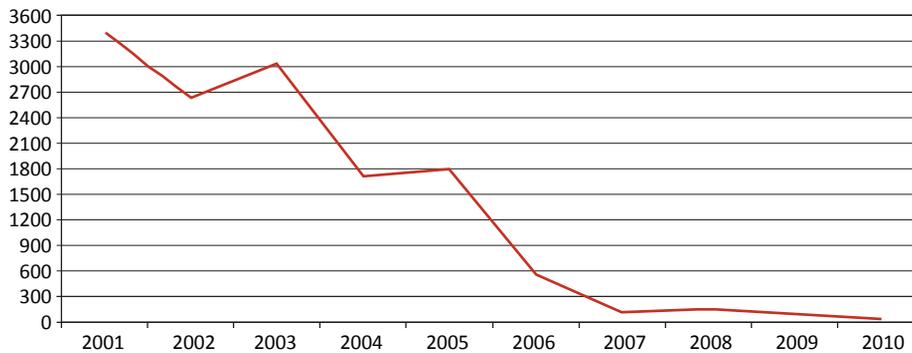
Nowadays, the number of malaria cases in the population has reached a very low level. In the last few years, reports coming from the communities show that cases were reduced to 37 within a population of approximately 50,000 people in 2011. In children under ten years old there were 4 cases of *P. vivax* and no cases of *P. falciparum*.

Figure1. Distribution of the medical clinics in Suriname, 2011



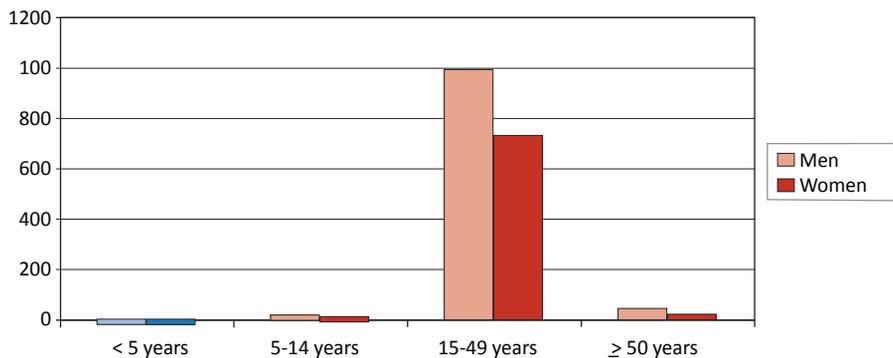
Source: Medical Mission.

Graphic 1- Evolution in cases of malaria in children under five years old, Suriname, 2001-2010



Source: Medical Mission.

Graphic 2 - Malaria cases by age and sex, Suriname, 2010



Source: Medical Mission.

## B) Gold mines zone: the experience of the community surveillance

The urgent services in the remote gold mines areas are possibly the most difficult in the fight against malaria in the Amazon region. The miners move frequently on two space scales. Short movements within a specific area in search of other places with a higher concentration of gold, and long movements, sometimes amongst countries, to buy basic inputs, visit their families or in the search of better opportunities in mining. In order to control malaria in mining areas, Suriname has created a system based on Malaria Service Providers (MSD, in English). It consists of a mining community trained to use malaria rapid diagnostic test kits (RDT, in English), prepare glass plates for quality control and offer treatment according to the results of the RDT. There were also trained to gather data over these people.

The surveillance system allows the selection of areas concentrating most cases and the identification of imported cases. Additionally, it also allows for the quality control of RDT in a individual way. Each result can be proven with a glass plate.

This innovative system that uses MSD workers in diagnoses, the malaria treatment, and the presentation of reports, financed by the Global Fund to fight AIDS, Tuberculosis and Malaria, has proven great success in the fight against malaria in Suriname. This diagnosis system and timely treatment for patients, close to where the miners live, has been widely successful in the reduction of malaria transmission within these areas and also in the prevention of the propagation in these communities.

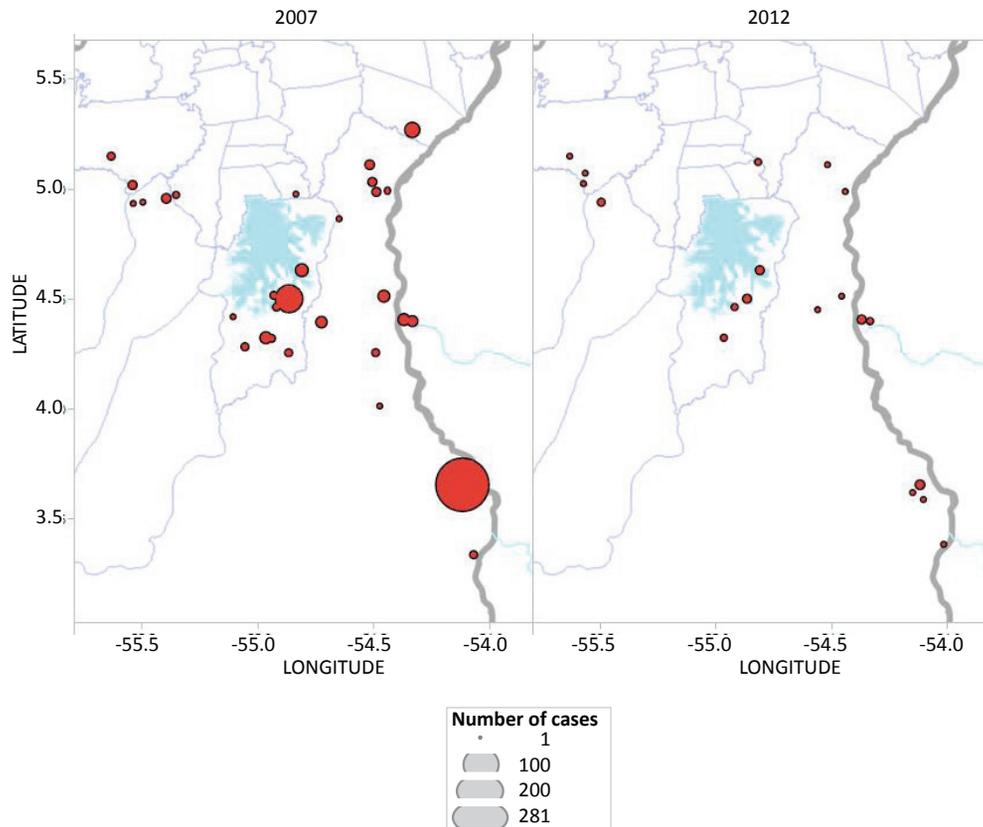
Picture 2- MSD worker in a mining area on the Suriname's countryside.



Source: Suriname Health Ministry.

Picture 3 demonstrates the reduction trend in malaria cases in the mining areas of the countryside according to what was reported by the MSD.

Picture 3- Evolution of these malaria cases in the gold mine areas, 2007-2012.



Source: Suriname Health Ministry.

### C) Diagnosed cases in the capital, Paramaribo

There are certain individuals, some from the communities but mainly from mining areas, who spend a lot of time on the capital, Paramaribo, because they specifically look for the diagnosis of symptoms similar to malaria. The majority of these cases were diagnosed by the Public Health Office's Public Health laboratory. Many miners staying at the capital had previously had their diagnoses from private laboratories or, even worse, they used self medication based on their own malaria experience. The majority of them used malaria medicines without a prescription. This situation changed when the Health Ministry opened up a clinic for the treatment of malaria (Tourtonne laboratory) in the neighbourhoods where most of the gold miners

temporally stay when they are in the capital. These miners come from Suriname’s countryside and mining camps in Guyana and French Guyana. The diagnosis and treatment are free. The data, the age, sex and camping site where they are from are collected by health workers and reported to the national malaria program.

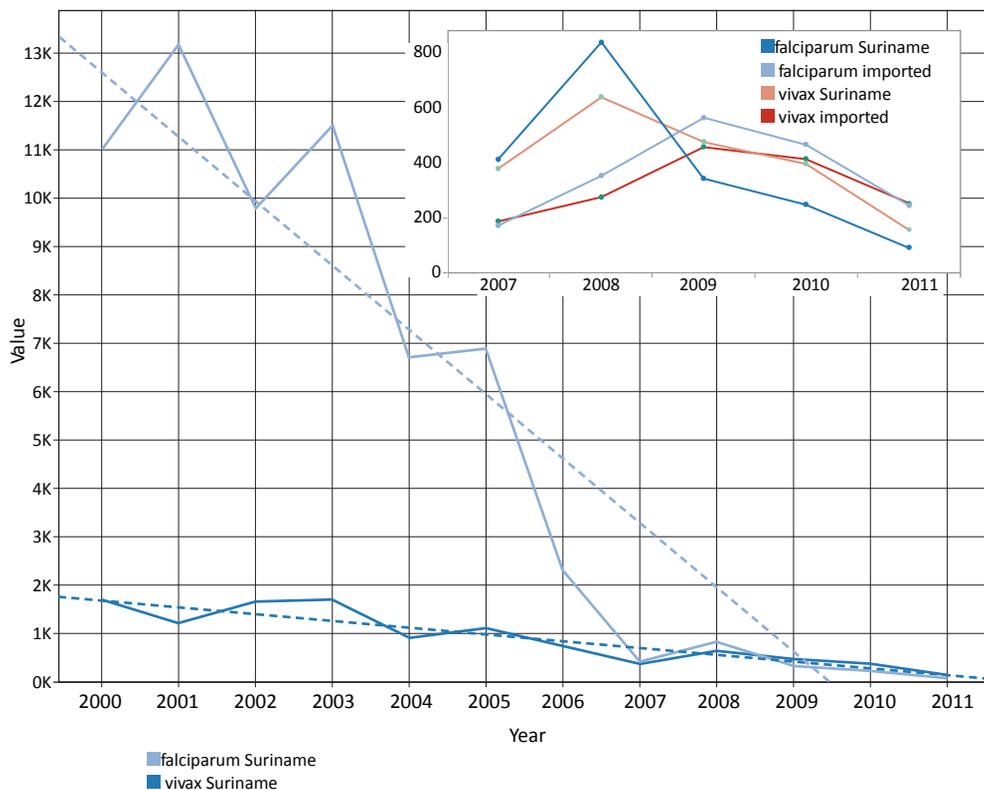
## EXPERIENCE ASSESSMENT

### Challenges for the control of malaria in Suriname

The data coming from these three sources (communities, gold mining, diagnosed cases in Paramaribo) are combined and analysed in order to improve the services.

The following graphic shows the reduction of malaria cases in Suriname in 2000-2011 and the imported cases since 2007. Nowadays, the increasing importance of the cases imported from Guyana and French Guyana are being registered by the surveillance system.

Graphic 3- Cases of Malaria in Suriname in 200-2011 and cases imported since 2007.



Source: Suriname Health Ministry.

With the continuous expansion of gold mining areas, even with the volatility of the gold prices, the challenge remains as to control the malaria in these areas. Those migrant workers crossing the borders in the Guyana Shield (Brazil, French Guyana, Suriname, Guyana, Venezuela) need diagnosis and adequate treatment. That will benefit not only the health of these populations, but also prevent the reintroduction of malaria transmission on those communities, besides of preventing resistance of the parasite against anti-malaria medicines. New results show the decline of the susceptibility to the *P. falciparum* to the anti-malaria treatment. Thus, is necessary to improve the cooperation within the Guyana Shield to harmonize, share and consolidate malaria surveillance data, focusing on the malaria transmission concentration areas and contain the resistance propagation.

The success of the malaria control in Suriname is a joint effort: together malaria could be eliminated from the Guyana Shield.

### **Surveillance in Severe Acute Respiratory Syndrome (SARS) in Belo Horizonte (Brazil): an opportunity to implement surveillance on hospitals<sup>IV</sup>**

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*Maria Tereza da Costa Oliveira*

#### **INTRODUCTION**

Belo Horizonte is located on the Southeast part of Brazil being the capital of the Minas Gerais State, with a population of 2,385,151 in 2010. Nonetheless 4.9 million people live in its metropolitan area. Belo Horizonte has 65 hospitals and 60 clinics, a total of 10,650 hospital beds. From which, 6,273 belong to the Unified Health System (SUS) while the remaining are on the private sector.

The 2009 A (H1N1) influenza pandemic, with the implementation of the surveillance in the case of severe acute respiratory syndrome (hospitalized) allowed for more approximation between epidemiological surveillance and the hospitals. Nonetheless, with the end of the pandemic in 2010, there was a decline in notifications. The explanation might lie on the virus low activity in 2010 and the fact that the Central Reference Laboratory (LACEN - MG, Ezequiel Dias Foundation) only performed testing for the identification of the influenza A (H1N1) virus pandemic in 2009, resulting in a great percentage of negative tests, which has discouraged the professionals to follow up with the reports.

In May 2011, the municipality received the support of the Health Ministry and the Pan-American Health Organisation (PAHO) for the implementation of the SARS surveillance in the hospitals including the increase of lab tests (immunofluorescence for the adenovirus, influenza A and B, para-influenza 1,2,3 and respiratory syncytial virus (RSV) for influenza A sub-categorized the pandemic virus, if necessary, the sample is sent to be sub-categorized in the National Reference Laboratory in Brazil Oswaldo Cruz Foundation - Fiocruz). PAHO gave the municipality all the lab equipment so it could process its own samples, as soon as the space adaptations are ready.

For a long time now, the municipality feels the urge to strengthen surveillance in hospitals, especially those considered strategic, and foster epidemiological surveillance centers within them. Only five hospitals (four public and one private) have surveillance centers. The surveillance center is a strategic partner of the municipality surveillance in the hospital and makes a difference in terms of mandatory notification events and those in an opportune manner. The municipal surveillance envisioned the opportunity to make this implementation through SARS surveillance and to support some of them, in the case they decide on constituting a surveillance center.

## OBJECTIVES

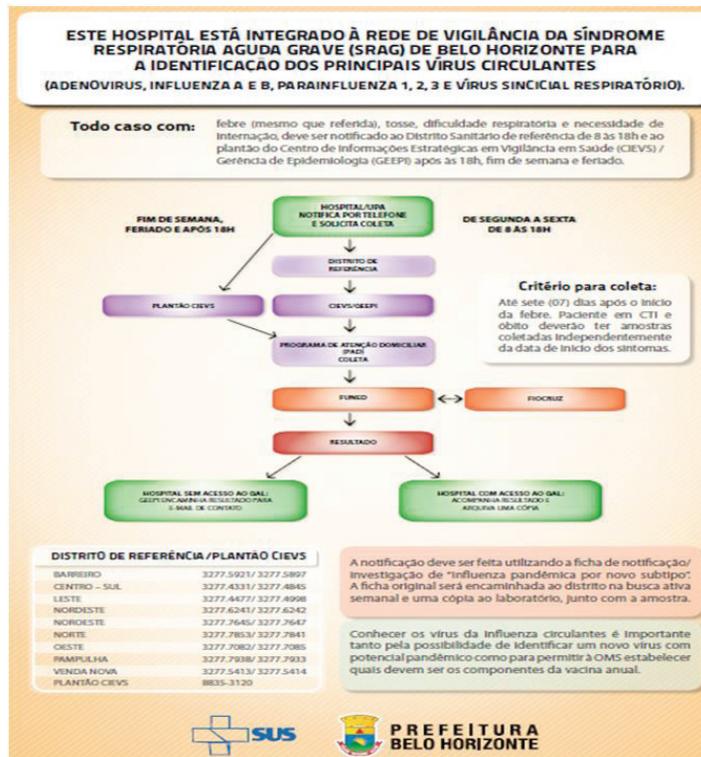
1. Identify the main current virus responsible for severe acute respiratory infections: Adenovirus, Influenza A (and its subcategories) and B, Para-influenza 1, 2 and 3 and respiratory syncytial virus infection;
2. Contribute to the strains of the influenza virus to the laboratories that are part of Net Flu of the WHO;
3. Enable the identification of a new virus with pandemic potential;
4. Institute pharmacological and non-pharmacological control measures;
5. Implement and intensify the hospital-based surveillance of diseases and important events to the public health.

## METHODOLOGY

Hospitals with over 100 beds (obligated to keep an Intensive Care Unit), totalling 32, were invited by the Health Secretariat to participate in a meeting where the intensification of surveillance of patients coming in the hospital with fever, cough and respiratory difficulties was proposed. In addition to it, all the municipal emergency units (UPA) were included.

Visits were paid to the hospitals in order to present the proposal to health professionals; posters with the work process and contacts were distributed, as the following examples:

Picture 1- Example of a poster for the prevention of various current viruses



Source: Belo Horizonte Health Department (SMSA-BH).

The Belo Horizonte Health Department (SMSA) has nine surveillance districts, where there is a Epidemiology Administration. In addition, there is an Epidemiological Administration located at the Information Centre for Health Strategies (CIEVS). All of them have participated on SARS surveillance, under the coordination of the CIEVS.

When a patient is hospitalized, the hospital should notify by phone the Surveillance District, available from 8 am to 5 pm Monday through Friday. For notifications on other days or time, they should call the CIEVS, available 24 hours every day (including weekends and holidays). The hospital should also fulfil the investigation report for the case, digitalized in the specific information system (Information System for the Notifiable Events -SINAN).

Then, the SMSA's Home Healthcare Programme (PAD) is called to come to the hospital to take a sample of respiratory secretion. It should collect the sample in the first 24 hours and it is responsible to take it to a laboratory as soon as possible. If not

possible (the laboratory doesn't take samples on weekends) the sample is frozen in one of the labs of the Emergency Units. The PAD is open every day from 7 am to 7 pm.

The hospitals receive the results in two ways: directly, those who access to the laboratory management information system (GAL); or are informed by the technicians of the CIEVS.

Every month, the whole network receives a newsletter by e-mail, also available on the Health Department's webpage, with an analysis of all surveillance data. Up to today, 16 newsletters were produced and distributed.

Picture 2- Belo Horizonte Health Department Newsletter

**SECRETARIA MUNICIPAL DE SAÚDE**  
DEPARTAMENTO DE VIGILÂNCIA EM SAÚDE E INFORMAÇÃO

**PREFEITURA**  
DE BELO HORIZONTE

**BOLETIM INFORMATIVO**  
SÍNDROME RESPIRATÓRIA AGUDA GRAVE (SRAG)

Nº 01 - Agosto de 2011

**INTRODUÇÃO**  
A vigilância de vírus respiratórios tem como objetivo identificar os principais vírus circulantes para propor medidas de prevenção e controle. Ênfase especial é dada aos vírus da influenza, devido à elevada morbimortalidade dos mesmos. Os vírus da influenza são transmitidos facilmente de uma pessoa infectada para outra, por meio de gotículas produzidas pela tosse, espirro ou durante a fala, além do contato das mãos com superfícies contaminadas. Segundo dados da última atualização da Organização Pan-Americana de Saúde, SE 48/2012, em relação à circulação dos vírus respiratórios, percebe-se aumento da atividade dos vírus da influenza na América do Norte com predomínio do subtipo H3N2 nos Estados Unidos e Canadá. Considerando os países da América Central e Caribe, houve um elevado percentual de positividade para vírus respiratórios em alguns países, com circulação de influenza A (H3N2), A (H1N1) 2009, influenza B e VSR. Na América do Sul a atividade da síndrome respiratória aguda grave (SRAG) permaneceu baixa e não houve mudanças significativas na região. Nos países andinos (Chile e Argentina), a atividade do vírus da influenza está ligeiramente maior que a esperada para esta época do ano. Até a SE 48/2012 observou-se co-circulação do vírus influenza B, influenza A (H3N2) e influenza A (H1N1) 2009. No Brasil foi detectado vírus influenza em 35 amostras processadas na SE 48/2012.

**NOTIFICAÇÕES, COLETAS E VÍRUS IDENTIFICADOS EM BELO HORIZONTE**  
Em 2012 foram notificados em Belo Horizonte 2.254 casos de SRAG, dos quais 1.418 (62,9%) são residentes no município (dados referentes até a SE 49/2012). A SE 29/2012 registrou um pico de notificação com 89 registros, seguido com queda. O menor número de notificações foi registrado na SE 48/2012 com 16 casos (Gráfico 1).

**Gráfico 1 - Notificações de SRAG, amostras coletadas e vírus identificados, Belo Horizonte, 2012**  
Em 2012 foram notificados em Belo Horizonte 2.254 casos de SRAG, dos quais 1.418 (62,9%) são residentes no município (dados referentes até a SE 49/2012). A SE 29/2012 registrou um pico de notificação com 89 registros, seguido com queda. O menor número de notificações foi registrado na SE 48/2012 com 16 casos (Gráfico 1).

Fonte: Secretaria Municipal de Saúde de Belo Horizonte. As amostras foram processadas pela FUNED e os resultados obtidos no SIA.

Foram liberados pela Funed 1.672 resultados de amostra de secreção nasofaríngea. Dentre as amostras processadas, 356 (21,3%) foram positivas para vírus respiratórios, sendo o VSR (163) e o vírus influenza (176) os mais identificados em 2012. O vírus influenza A foi identificado em 151 amostras (49 (H3N2), 99 (H1N1) e 3 no subtipo), o influenza B em 25, o VSR em 163, 11

Source: Belo Horizonte Health Department (SMSA).

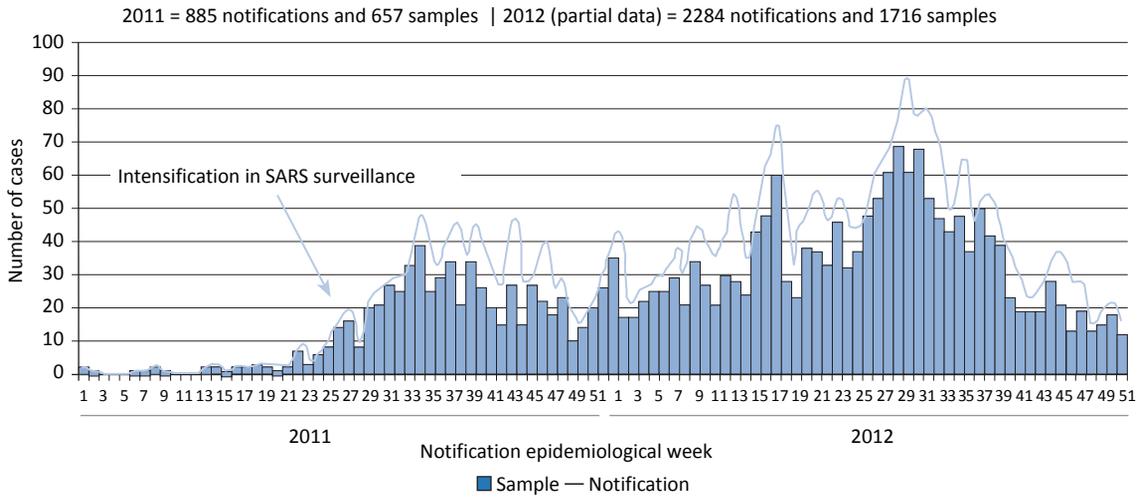
## EMPLOYED RESOURCES

The financial and human resources applied for surveillance were those of the SMSA. Nonetheless, Normative Instruction MS number 2.693, November 17th 2011 has brought additional financial resources (US\$ 50.000 for implantation and US\$ 10.000 every month for maintenance), allowing the establishment of agreements with the other five hospitals and the distribution of resources to the SARS surveillance in the UCI, as an incentive, and with the additional commitment of the hospital to constitute a epidemiological center.

## RESULTS

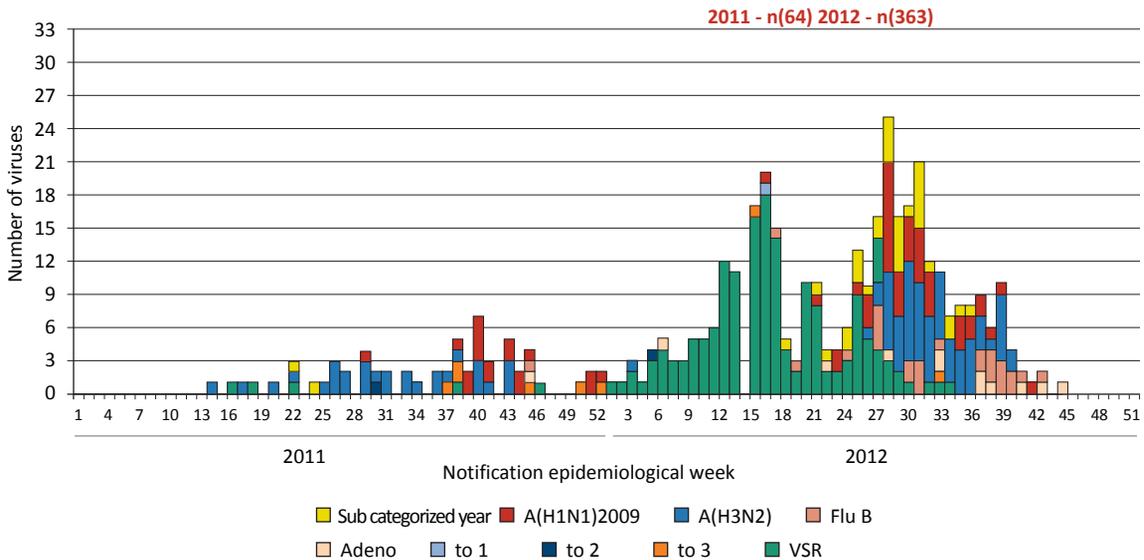
The joint effort of the hospitals to SARS surveillance, as shown in the following graphics 1 and 2, was increasing. During 2011, beginning on the implementation in June, 885 cases were notified, 657 samples taken and 64 viruses identified. In 2012, up to this week (partial data) 2,284 were notified, 1,716 samples taken and 363 viruses identified.

Graphic 1- Notifications and samples collected from the SARS, Belo Horizonte, 2011-2012



Source: Influenza/GVSI/GEEPI/SMSA/PBH 19/12/2012

Graphic 2 – Respiratory viruses identified, SARS surveillance, Belo Horizonte, 2011-2012



Source: Influenza/GVSI/GEEPI/SMSA/PBH 19/12/2012

The PAD, whose mission is to provide home care to critical patients in order to diminish the levels of hospitalization or give continuity to hospital treatment, has been a fundamental partner for the sustainability of the SARS surveillance. Moreover, it has allowed for a greater opportunity in sampling. Over 96% of the samples have been taken within the first 24 hours of the notification.

Generally speaking, we can observe that 2012 has seen a predominance of Respiratory syncytial virus (RSV) from the beginning of the year up to the week 27, when the virus is replaced by the circulating virus influenza.

Before observing the evident circulation of RSV, which started in January and not in April as thought, the municipality requested the Health Department of the Minas Gerais State to evaluate the release the Palivizumab medicine, specific for the prevention of RSV infection in eligible children, since the beginning of the year and not only starting in April, as scheduled on the SES-MG Resolution numbered 2417 from July 16th, 2010.

As a consequence of the finding of a bigger quantity of influenza virus activity in the beginning of week 27, it was decided to maintain the vaccination against influenza in pregnant women up to the end of July, especially to reach those who found out they were pregnant after the campaign carried out in May, though still in a high virus activity period. The Oseltamivir distribution was also implemented, and made available in all health services, including hospitals.

The surveillance has allowed a closer approach to hospitals. Fulfilling their demands, two epidemiological surveillance trainings, with emphasis in SARS surveillance, were offered in April and August of 2012 to seven hospitals. Since then, professionals in hospitals with this center or willing to have these centers have participated in a monthly municipality epidemiological surveillance meeting. Four hospitals already constitute centers as subscribers of the SMSA agreement.

## **EXPERIENCE ASSESSMENT**

The implementation process of SARS surveillance has been nonstop since the beginning in June 2011 and has allowed the integration between epidemiological surveillance and hospitals. Municipal participation was fundamental to achieve these results, collecting samples in a timely manner, training the personnel in hospitals, providing on-going feedback and counting on an effective laboratory response (FUNED). As a consequence, the hospitals have been systematically notifying; four major hospitals have joined the proposal of constituting hospital centers.

This surveillance has propelled the integration amongst sectors of health surveillance, including laboratories, the Homecare Program and the hospitals.

They have contributed to knowledge on the virus circulation in the municipality throughout the year and to propose measures of prevention and control.

Therefore, the experience consolidated in Belo Horizonte is considered a successful one.

## Control program for major endemic diseases – Dengue in Brazil<sup>V</sup>

*Fabiano Geraldo Pimenta Júnior*

### INTRODUCTION

In Brazil, the programmes to control major endemics, amongst them dengue, were historically marked by a vertical structure and developed through the “sanitary campaigns” model.

In the model proposed by the Brazilian Unified Health System (SUS), there is no space left for those fragmented and divided programmes. In the contemporary scenario, the main objective of the dengue control program is to avoid deaths caused by this disease and to maintain the levels of infestation by the *Aedes aegypti*, avoiding the occurrence of endemics, which is only possible in an integral and conclusive system, aimed at the primary healthcare.

This integrated and comprehensive approach is expressed through the dengue control contingency plans, where the responsibilities of the different areas should be clearly defined for each of the situations and levels of transmission. Nonetheless, the main challenge is not to build a plan with these attributes, but to guarantee its execution in a coordinated, organized and timely way.

In Belo Horizonte, capital of the Minas Gerais State, with a population of 2,375,444; the first indigenous dengue cases occurred in 1996, when 1,806 cases were confirmed. DENV-1 serotype was isolated. On the same year, the disease was endemic in the municipality, with endemic occurrences, like in 1998, when 86,893 cases of DENV-1 and DENV-2 were confirmed.

Over the years, the serotypes DENV-1, DENV-2 and DENV-3 have circulated in the municipality. However, in 2012 the DENV-4 was introduced, which enhances the endemic risk, because of the population’s susceptibility to this serotype.

## OBJECTIVES

In a scenario where the vaccine is not available, the only way to avoid dengue epidemics is to maintain low levels of vector infestation. Therefore, these are the main objectives of the program:

- Develop a greater capacity to predict the areas of danger in the municipality, prioritize integrated actions of prevention and dengue control;
- Carry out a systemic work of dengue control, aiming to implement all the possible strategies, the so-called integrated control;
- Early detection of areas with high intensity transmission rates, to avoid occurrence of epidemics;
- Avoid dengue fatal cases.

## METHODOLOGY

For the control of dengue epidemics, it is fundamental the early detection of any unusual epidemiological situation of the disease.

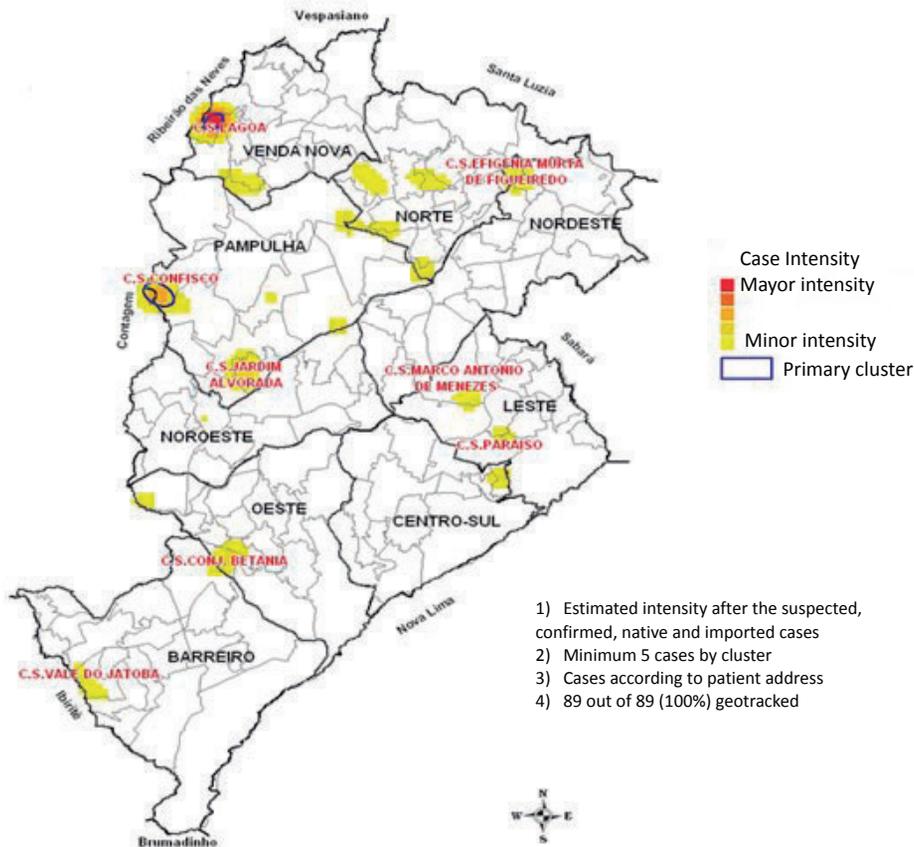
In the face of a structured surveillance service, the day-to-day analysis of the data produced by the system allows for the timely identification of an increase in the cases trend in a certain location. This identification is the key point to be observed over time.

Belo Horizonte implemented the weekly analysis of the epidemiological situation, layered by every covered area in the 147 existing healthcare centers in the city, which allows the location of the current cases. The cases added in the minor areas permitted directing actions to fight the vector, in a comprehensive manner, and also a better organization of patients care.

In order to obtain a better integrality, opportunity and consistency of the information, there is an integration amongst the health complementary nets and the private nets, the notification system and information of the results of the serological tests, with a flow that allows for the reception and daily analysis of the notified cases, with the option of simplified notification for outside patients.

Following a map (Kernel map) exemplifying the analysis weekly carried out by Belo Horizonte's Health Department.

Picture 1 – Intensity of the dengue suspected and confirmed cases, Belo Horizonte, October 2012.



Source: Sinan Online (up to 23/10/2012)/GEEPI/GVSI/SMSA-BH

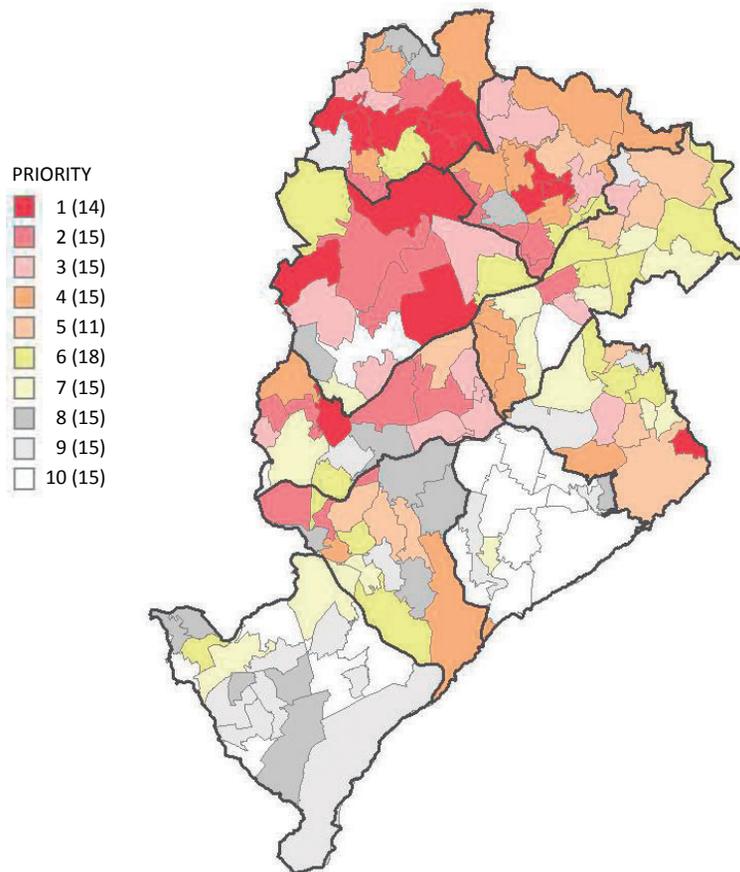
The goal of the map is to identify the areas of major concentration of suspicious cases, with the intention of quickly trigger research and control actions.

In order to elaborate the map the cluster detection methodology was applied by the method of closer neighbourhood. This method identifies added points that are closer especially if they were randomly distributed. In this hierarchical manner, the first identified are the primary clusters, represented through ellipses. Following the centroids of every ellipse are treated as in the first stage and a agglomerate of primary clusters constitute a secondary cluster. This proceeding is repeated until no cluster is found.

Aiming towards perfecting the control actions, beginning in 2010 the Belo Horizonte Municipal Health Department started crafting a risk map based on the

numerous indicators such as the incidence in a year; history of the results of Fast Research of Infestation by the *Aedes aegypti* (LIRAA); percentage of edifications in a ground level; average of eggs in the egg tramp (starting on August of the current year), allowing for the optimization of the existing resources and the prioritizing of the intersectoral actions, such as: the cleaning task force, educational actions in schools, the recollection of tires, among other.

Picture 2 - Dengue Risk Map, Belo Horizonte, November 2012.



Source - GEZOZ/GVSI/SMSA/BH.

## RESOURCES USED

The SUS- BH network is organized into nine health districts and has 147 Health Centers, 578 Family Health Teams (covering 82% of the population); 2,400 Community Health Agents; 1,087 Family Health Program (PSF) complementary professionals; Central Laboratory, eight emergency units and six on contract; one own hospital and 33 under contract. The family health strategy covers 82% of its population.

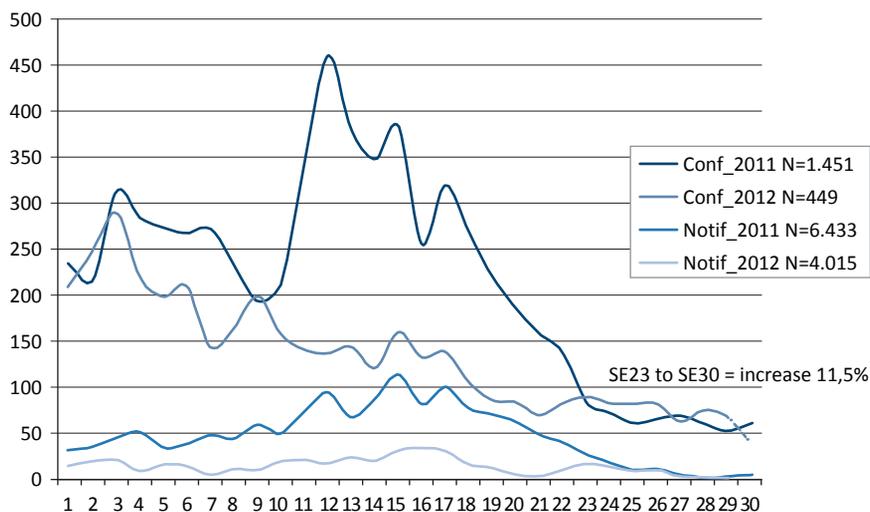
To carry out epidemiological and entomological surveillance actions, and fight against the vector, the Municipal Dengue Control Program counts with 12 Epidemiological Surveillance technicians, 82 Zoonosis technicians/coordinators; 1,372 Agents to Combat Endemic Diseases I - ACE I; 207 Agents to Combat Endemic Diseases II -ACE- II, 168 Support Points, a Zoonosis Laboratory and 87 vehicles.

The municipality invests annually around 12 million dollars in dengue-fever prevention and control, of which 60% come from the Health Ministry through the Health Surveillance and Promotion Fixed Floor, which is funded for all municipalities in order to support the implementation of Health Surveillance actions. The remaining 40% comes from the Municipality itself, which has currently allocated approximately 20% of its budget in to the health field.

## RESULTS

The expected result is to prevent the occurrence of dengue epidemics through a contingency plan, with associated indicators, which will allow the municipality to conduct a systematic monitoring on the status of the disease transmission, the early detection of unusual situations and setting the corresponding priority for intensifying actions to combat vectors and make the necessary adjustments in the care network for the treatment of dengue patients. As seen in Graphic 1, the trend of cases in the municipality within the past two years is decreasing.

Graphic 1 - Cases notified and confirmed, Belo Horizonte, EW 1 to EW 30, 2011 and 2012.

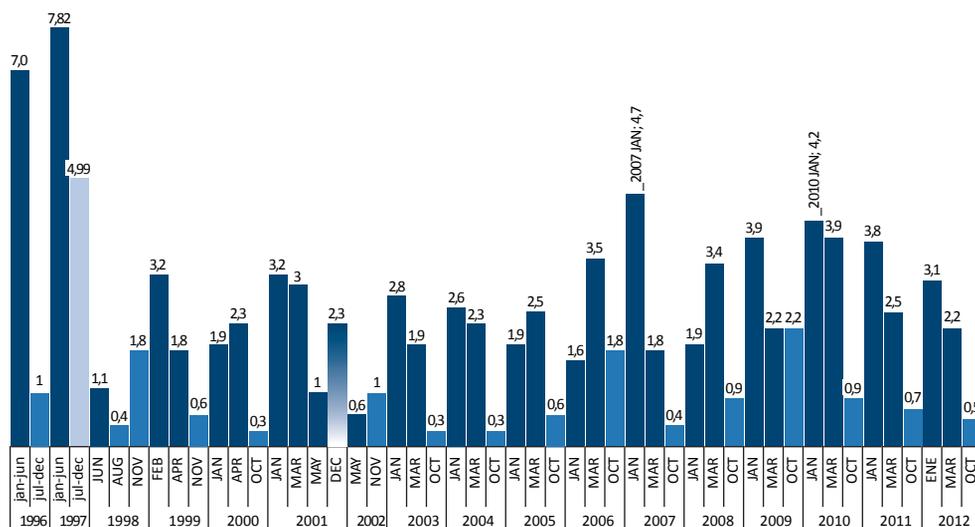


Source: Sinan Online (until 08/13/2012).

Another important result is the reducing trend on *Aedes aegypti* infestation rates when compared with the results of the surveys (LIRAA) conducted, since 2010, in same periods of previous years, as shown on Graphic 2.

Likewise, the municipality has prioritized the comprehensive care of patients. The treatment protocol for patients with dengue-fever was modified in order to contemplate a care line based on risk classification, thus providing differentiated service to those with comorbidities (hypertension, heart disease, and diabetes, among others) or risk factors (pregnancy, children and elder people). The protocol is widely reported to health professionals, who are trained continuously. The Quick Attention units, which are part of the reference system, perform the dengue diagnosis quick test (NS1) on suspected cases. As a result of this effort, no dengue related deaths were reported among residents treated at the Belo Horizonte’s health network in the years 2011 and 2012.

Graphic 2 - LIRAA, from 1996 to 2012, Belo Horizonte



Source: GEZOZ/GVSI/SMSA/BH.

## EXPERIENCE ASSESSMENT

A prerequisite for the implementation of this strategy is the systematic involvement of the decentralized epidemiological surveillance teams in close coordination with central level technicians in order to give greater opportunity to the notification and investigation of cases, thus identifying immediately the areas with higher levels of transmission, so that control actions can be faster and more effective.

There was a notorious reduction of vector's infestation rates and cases detected in town within the last two years. Likewise, no dengue related deaths were detected in the past two years. Therefore, the practice has shown that the integration of epidemiological and entomological surveillance and the assistance network (primary, emergency and hospital care) is feasible, and carries clear benefits for the population.

## Innovative Experiences in Sanitary Surveillance

### Educanvisa: a Brazilian experience in Sanitary Surveillance<sup>VI</sup>

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*Alice Alves de Souza; Claudia Passos Guimarães Rabelo;  
Daniella Guimarães Araujo; Maria de Fátima Ferreira Francisco;  
Rosaura Maria da Costa Hexsel*

## INTRODUCTION

In Brazil, the Unified Health System (SUS) is an inclusive system based on the broader concept of health, social participation and the construction of public policies for health promotion. The SUS has brought many improvements to the health of Brazilians, however, there are still many challenges that SUS managers and users have to face. Among public health problems, one of the most serious is the misuse of drugs, including self-medication and its consequences. The data provided by the National Toxic-Pharmacological Information System (SINITOX) reveal that drugs have been leading the cases of human poisoning in Brazil for over 10 years. The indiscriminate and often unnecessary use of these products, under the stimulus of advertising and self-medication culture, creates the need of informing and warning people about the risks and the precautions to be taken in the use of drugs.

Another issue of growing concern to the authorities, managers and health professionals is obesity, which is considered a multifactorial chronic disease and a risk factor for the onset of many other chronic diseases. The Health Ministry's annual telephone survey/research "Risk Factors Surveillance and Chronic Diseases Protection (Vigitel)" conducted in 2011 revealed that the number of Brazilians who are overweight is equivalent to almost half of the population (48.5 %), while 15.8% are obese.

In keeping with its mission of promoting and protecting the health of the population, the National Health Surveillance Agency (ANVISA) has several responsibilities, including the supervision of advertising of products subject to sanitary surveillance in order to prevent, avoid or eliminate health risks caused by the influence of unfair or deceptive advertising transmitted in different media.

In order to control the maximum number of advertisements, the Agency developed a project in 2002 in partnership with higher education institutions in different states, so that advertising could be collected and sent to ANVISA for analysis. Among its many results, some indicated the need to adequately inform the public about the consumption of products subject to sanitary surveillance.

The health measures should not be limited to police power, such as the monitoring, authorization and punishment of crimes. To effectively accomplish its mission of eliminating, reducing or preventing public health risks, surveillance should develop, on daily basis, educational activities focused on awareness and guidance for the population. The alignment between supervision and education in terms of sanitary surveillance provides an interactive relationship between the State, manufacturing sector and society, plus it causes the essential change of attitude towards the protection and promotion of the population's health.

Following the aforementioned patterns, the "Educanvisa Project: Sanitary Surveillance Education" was created. It is an educational activity that has been training teachers and sanitary surveillance professionals since 2005 in order to promote proper use of medicines and food within the school community.

The school community is an environment that encourages discussion, participation and plays a key role in preparing people for adult and public life so they can exercise a full citizenship. As a privileged space it is, the school can develop strategies involving both the educational institutions and its environment in order to improve the living and health conditions of the populations.

## **OBJECTIVES**

Educate the school community about the risks associated with the inadequate consumption of products subject to sanitary surveillance, which are usually influenced by advertising, by including surveillance in the curriculum of public schools participating in the Educanvisa program.

## METHODOLOGY

The insertion of localities in the Educanvisa program started with localities expressing their interest by sending a letter or email to ANVISA requesting to be part of the project. Then, ANVISA conducts a meeting with representatives of both sanitary surveillance and the Education Secretariat in order to introduce the project and designate the Educanvisa local coordinators.

The partnership is formalized through an acceptance letter signed by ANVISA, Local Sanitary Surveillance, and the Health and Education's Secretariat. In some cases, it also involves the participation of a higher education institution.

The number of teachers to be trained in each location is defined according to the availability of training funds for the event. The courses, which are taught by the technical team of Educanvisa, are carried out in two days in which the following topics are discussed: sanitary surveillance and its importance in people's daily life, eating healthy and food care, self-medication, advertising influence on drug and food consumption and its health risks, and the rational use of drugs with special attention to inappropriate or unnecessary use of medicines.

Trained teachers develop the project in the classroom and work with students on the topics covered during training. These educators must meet more than 75% of the activities proposed by Educanvisa to receive an ANVISA's Statement of Completion for a total of 120 hours. Local coordinators also receive a 120-hour statement after submitting to the Agency a final report containing the results on how actions developed in their municipality.

To finish the project's activities and with the aim set on promoting the exchange of experiences among participants and other partners, a national meeting is organized so that results can be presented.

## RESOURCES USED

The Educanvisa project is developed thanks to the Agency's resources and the fundamental collaboration of local sanitary surveillance organs and education departments. Likewise, ANVISA provides teachers with all materials needed for the project.

## RESULTS

### Expected results

- To train basic education teachers in public schools, sanitary surveillance professionals, and the Health and Education's Secretariat, in all subjects related to proper consumption of products subject to sanitary surveillance, with the focus set on thinking the influence of advertising on the acquisition and use of these products.
- Teach in classrooms all topics covered during training.

- Widespread awareness within the school community.
- Integration of Sanitary Surveillance and the school community.
- Institutionalize the sanitary surveillance issue on schools.

## Results Obtained

Between 2006 and 2012, the Agency's health education projects, which are currently managed by Educanvisa, have served more than 90,000 students from 919 public schools in Brazil and has promoted the training of 2,741 teachers, 338 sanitary surveillance professionals, and 223 Education Departments.

According to reports submitted by the project's coordinators, students made brochures on health promotion, and bookmarks and refrigerator magnets containing the guidelines on proper and rational use of drugs. Furthermore, they created skits about drug advertising and regulation that were played during the parents' bimonthly meetings.

Educanvisa topics have been developed in various curriculum areas. Thus in Portuguese class, students explored new vocabulary words; in Science they studied and discussed health inspections; in Geography they conducted activities to determine the location of laboratories and pharmacies; in History they studied the development of drugs over time, while in Mathematics they performed calculations in accordance with the contents and dosages of medications.

The desire for change was a unique characteristic perceived at the school communities involved in the project. A simple example of this attitude was the closure of the unofficial pharmacies that were still present at schools. With the collaboration of the Strategy for Family Health program, students were referred to health centers in their communities for treatment.

At one site, a puppet theatre was built so on children's week the students performed a play called "The risks of self-medication", in which they warned about the importance of always seek medical treatment and never use medications without a professional prescription. These activities were aimed to those students that were not directly involved in the project, through a playful presentation of the issues discussed, especially those related to health-care.

## EXPERIENCE ASSESSMENT

Since February 2012, the Educanvisa project was assigned to the Agency's Education, Research and Knowledge Centre (NEPEC). The model has currently been revised with the aim of restructuring it in order to expand the topics worked with teachers (pesticides, disinfectants, cosmetics, counterfeit drugs, among others).

The idea is to find a model in which the project will be self-sufficient and less dependent on the financing of the Agency.

## Anmat Observatory<sup>VII</sup>

Julietta Curbello

### INTRODUCTION

For modern nation states, it is essential to count with objective, reliable and timely information in order to elaborate complex diagnostics of situations, as well to support strategic planning policies and guide the decision making process in order to improve the citizens' living conditions and life quality.

In this scenario, the National Administration of Food, Drugs and Medical Devices in Argentine (Anmat) implemented its Observatory<sup>4</sup> in November 2010. It is an innovative management tool that allows a closer and more powerful relationship between the Regulatory Agency and the various actors in the health field, for generating information based on scientific evidence to guide the decision-making process.

### OBJECTIVES

The observatories have shown an increasingly prominent role in a growing number of institutions, but their designs depend on the objectives and needs of the organization, thus there is no single definition of these instruments.

However, some definitions are applicable to the Anmat's concept of observatory:

*“An observatory represents the organization of an intersectoral monitoring network. Its main goal is get to know events more deeply, know its determinant factors and the effectiveness of intervention measures”<sup>5</sup>.*

*“An observatory is focused on providing effective information for taking health-related decisions and actions, and more specifically on providing information and knowledge for policies and decision-making processes based on evidence.”*

*“It is a tool oriented to policies that operationally intends to conduct a comprehensive monitoring and a systematic and continuous reporting on relevant aspects of the population's health and the health systems, in order to support in an efficient manner and based on evidence - the development of health policies and plans, and the decision making in public health and health systems. The ultimate goal is to contribute to the preservation and improvement of the population's health, including reducing inequalities”<sup>6</sup>.*

Moreover, these information devices represent important epidemiological

surveillance strategies, which are defined as “*the systematic, continuous, timely and reliable collection of relevant and necessary information of some of the population’s health conditions. The analysis and interpretation of data should provide the basis for decision-making, and at the same time be used for its dissemination*”<sup>7</sup>.

From this perspective, the Anmat Observatory commits its work towards promoting active sanitary surveillance since it anticipates the appearance of possible problems, identifies the already existing problems, defines the scope and proposes alternative solutions jointly through the information generated at its forums.

The Anmat takes the vision, experience and knowledge of those working in the public health field in a plural, participatory and multisectoral manner and through its daily practices related to medicines, food, cosmetics, dietary supplements, and medical devices.

The joint work allows, on one hand, to develop a comprehensive and complex vision of the national and international health scenarios, and the many factors that can influence on health. On the other hand, it allows to implement courses of action that are based on the actual needs of the different sectors, and not on mere *a priori* assumptions, since they are proposed by those involved from knowledge and daily experience.

The information obtained serves to define the agenda of priorities and establish collaborative and cooperation actions between different institutions, which favours the generation of networks and communication-flows between different institutions and sectors that had no connection so far.

Moreover, this information is available on the Observatory’s mini site within the Anmat’s institutional website, thus enabling its social use.

This is highly important because the information was generated collectively, so it must be published and available for actors that are part of the process and also for citizens, who have the right to know in a transparent and clear way the actions the government is implementing, and moreover to participate actively.

## STRUCTURE AND METHODOLOGY

The Observatory’s structure consists of a general coordination and two levels –called primary and secondary depending on the type of sources that generate the information.

The primary level generates direct “one-source” information, but it is validated by integrating other sources of information.

It is organized as “Participative Diagnostic Forums” and meetings with various institutions such as professional associations, universities, schools, government agencies, NGOs, and all types of institutions that due to their activities are linked to products under Anmat’s surveillance.

The secondary level receives data generated by other technical areas of the Administration in order to organize, systematize, interpret and communicate it to the different technical areas and agencies.

Its main purpose is to build a general matrix of indicators from the data sent by the various Anmat's surveillance systems (Food Surveillance, Pharmacosurveillance, Odontology Surveillance and Technological Surveillance).

The generation of indicators allows the elaboration of descriptive analyses for the current scenarios, setting trends and making forecasts.

## RESULTS

A total of 120 activities were conducted since its creation including Participative Diagnostic Forums and meetings, which involved the participation of 205 people. A total of 92 institutions are actively involved, thus representing a wide range of sectors.

As an example, we shall present three results. The selection reflects the seek of representativeness in terms of products that are under the Agency's responsibility.

### 1. Drug labeling

During the forums conducted with the Hospital Pharmacists Association and the Argentine Nursing Federation, among other Observatory's work spaces involving professionals from different specialties, it emerged as an issue the existence of similar labeling (font, colour or even the container's shape) for drugs with similar characteristics, but with completely different active ingredients. This situation represents a serious danger to the patients' health and could lead to serious medication errors.

As a result, and after reaching consensus, a rule<sup>8</sup> was made in order to set all the conditions and colours that labels should carry on primary packaging for small-volume electrolytes parenteral solutions.

At the moment we are working on the development of an Anmat's Disposition that will collect and systematize all the drug labeling criteria set by the very same Anmat<sup>9</sup>.

Another drug labeling related problem identified and solved in the framework of the Observatory, was that of the individual identifications on solid oral forms' blisters.

The premise made by the hospital health professionals was that since solid oral forms are packaged in blisters, everytime a form is separated from its primary container, all the pharmaceutical active ingredient information gets lost along with the dose, number of batch, expiration date, and other data that could lead to errors in storage, dispensing, distribution and administration of medication.

As a result, an Anmat disposition was developed. It establishes that primary packaging (blister packs) of solid oral forms that are intended for hospital use and distribution must be die cut so as to allow the division of the primary packaging in each dosage unit thus preserving the product's unique identification, traceability and expiration date. The containers shall be printed with the following information in each unit dose: International Nonproprietary Name (INN), Argentine Nonproprietary Name (DCA) of the pharmaceutical active ingredient, dose, lot number, expiration date, and laboratory's name.

This result has the advantage of preventing the counterfeiting, alteration or modification of the medication since the drug is identified individually throughout the distribution chain.

## **2. Healthy Food Propriety Declarations**

The Forum "Healthy Food Propriety Declarations", which gathered representatives of the Argentine Society of Nutrition, the University of Buenos Aires' Pharmacy and Biochemistry School, the National Scientific and Technical Research Council (CONICET), and technicians of the Regulatory Agency -specifically the National Food Institute (INAL), was organized since the Regulatory Agency identified the need of having a regulation tool in order to establish the criteria for the presentation and scientific evaluation of Healthy Food Propriety Declarations. As a result, we developed a guideline for the presentation and scientific evaluation of Healthy Food Propriety Declarations<sup>10</sup> that applies to all food advertising that refers to health declaration. Plus, its main goals are to evaluate all scientific evidence that support these health declarations, and standardize the evaluation process.

Likewise, during this forum it was decided the creation of the Evaluation Committee for the Authorization of Healthy Food Propriety Declarations<sup>10</sup>. This committee is responsible for implementing the afore mentioned regulations, and has also the role of evaluating and issuing reports advising the Anmat on the documentation submitted by companies that require authorization for the use of health declarations in the messages that advertise their products.

## **3. Internet based illegal trade of medicines and illegitimate medical devices**

In August 2011 the "Risks and Impacts of Health Products Marketing Forum" was held. It had the participation of representatives of the pharmaceutical industry, the Crimes and Criminal Analysis Division of the Argentine Federal Police, the Ministry of Foreign Affairs, International Trade and Worship, and the Argentine Pharmaceutical Confederation, among other institutional actors interested and

involved in the fight against the Internet based illegal trade of medicines and illegitimate medical devices.

The forum had been preceded by the “Interdisciplinary Forum of Strategy Assessment to Fight Counterfeit Drugs and Illegitimate Medical Devices” held in December 2010 in which was established, as a central concern, the increasing number of internet based offers of human-health products that are regulated by Anmat, something that’s illegal in the case of drugs<sup>11</sup> and highly risky in the case of medical devices considering the large number of existing illegitimate products.

As a measure to strengthen the fight against internet based trade, the Anmat signed an agreement with MercadoLibre and DeRemate.Com websites, in which the Agency agreed to oversee the deals offered on these sites in order to prevent products being displayed improperly. In turn, both companies agreed to terminate the advertising on such products and provide the Anmat with the sellers’ information so appropriate measures can be taken.

Since the signing of the agreement, the “Monitoring and Enforcement Programme for Advertising and Promotion of Products Subject to Sanitary Surveillance” detected and audited a total of 370 illegitimate deals on Mercado Libre, being 90 percent related to medicines.

This measure represented a high impact on public health since such deals are potentially dangerous for consumers, who find it difficult to identify the origin of the products and the storage and distribution conditions.

## **EXPERIENCE ASSESSMENT**

We believe that the actions conducted by the Observatory within the institution and in company of the appropriate sectors, helped to create a culture of both joint and interdisciplinary work, which put together encouraged cooperation and strengthened the bonds of trust.

While this tool has little implementation time, it has already proved to be extremely successful, which encourages us to set new challenges.

The next step, and possibly one of the most important, is to organize people’s forums. These meetings will aim to inquire about the representation and behaviour of citizens regarding products that concern to the Anmat, and at the same time they will serve for listening to suggestions and proposals.

## Health Technology: Insertion Assessment and Surveillance<sup>VIII</sup>

*Catherine Ausqui; Salomé Fernandez; Susana Novaro*

### INTRODUCTION

The use of health technology requires scientific evidence to reduce the uncertainty associated with its use. They also need to incorporate the cultural, social, economic and family contexts of both patients and institutions where these technologies are applied. There's no doubt that medical science and health technologies have introduced significant changes in the provision of services, plus they have contributed significantly to increase life expectancy, improve the population's health and build a better way of life in societies<sup>12</sup>.

Also the growing importance of non-communicable diseases is reflected in the continuous incorporation of technology into medical practices and health care since it allows greater diagnostic capacities, plus it allows more complex and effective therapeutic interventions<sup>13</sup>.

Commonly, there are five stages that can be distinguished in the life cycle of technology: innovation, diffusion, incorporation, technosurveillance and abandonment. We will focus on incorporation and technovigilance<sup>14,15</sup>.

Since 2005, Uruguay started a structural reform in the health sector that was consolidated in 2007 with the approval of the National Integrated Health System (SNIS). Among its main objectives we can mention the following: improve equity in terms of population's access to health services, respond more effectively to health needs, provide quality services and achieve efficacy of the system by ensuring the accessibility, quality, equity and universality of health services. The reform has three main areas in which to work: changing the service model, changing the funding model, and changing the management model.

The reform introduced new policies for promoting a rational use of health resources by strengthening the health technology assessment, and evaluating all clinical, epidemiological and cost aspects as well the social impact caused by health interventions, technology incorporation and health interventions in general (services, drugs)<sup>16,17</sup>.

In this way, the Public Health Ministry becomes more demanding and communicates to all public and private health institutions the need of focusing on quality, effectiveness and efficiency of health interventions.

Therefore, the challenge has been to find ways so that either the new or already existing health technologies could fall within the premises of the health system's reform, following and adapting the health technology assessment models that are being imposed worldwide.

## OBJECTIVES

This approach intends to guide the use of health technologies in Uruguay according to needs, avoiding duplication, prioritizing decentralization so it can be disseminated to the rest of the country, and ensuring universal accessibility. Also, it must achieve a rational use of human, material, and financial resources, as well a rational use of the future and already existing healthcare capacities.

Likewise, it was established which medium and large size medical devices, and medium and high complexity health services require authorization prior to be incorporated:

1. Linear electron accelerator.
2. Angiography.
3. Extracorporeal circulation pump.
4. Cobalt pump.
5. Gamma camera.
6. Echocardiography.
7. Dialysis equipment.
8. “C-arch” radiological equipment.
9. Robotic Surgery equipment.
10. Ophthalmological use equipment.
11. Extracorporeal lithotripter.
12. Mammography.
13. Magnetic Resonator.
14. CT scanner in all types, including positron emission and dental.
15. Innovations.
16. Incorporation of equipment not available in the country.
17. Surgical block.
18. Childbirth room.
19. Intensive care unit.
20. Imaging.
21. Specialized services.
22. Primary care services.
23. Mobile emergency.
24. Clinical analysis laboratories.

## METHODOLOGY

The main source considered for making the questionnaires was the “Guide for the Acquisition of New Technology” (GANT)<sup>18,19</sup> used by the Andalusian Agency for Health Technology Assessment. The questionnaire consists of five modules that collect the most relevant data: description of the technology or service proposed, clinical characteristics and indications, effectiveness and safety data, impact on the organization and service management, and economic valuation.

Questionnaires should be completed by the requesting services primarily, but it is advisable to work with other units or areas related to the process, information systems, research or epidemiology units, as well with areas capable of providing data for economic valuation.

## RESOURCES USED

The entry process for new technology incorporation assessment applications involves different areas and professionals within the interdisciplinary approach that the Health Technology Assessment (ETS) demands.

In order to incorporate Medical Devices or Health Services, the Integral Provider must submit an application letter to the Public Health Minister, completing and attaching the corresponding form that’s available on the Public Health Ministry’s website ([www.msp.gub.uy/productosdesalud/tecnologiamédica/incorporacióndetecnología](http://www.msp.gub.uy/productosdesalud/tecnologiamédica/incorporacióndetecnología)).

Professionals working in the Technology Assessment Department (DET) are trained in the Health Technology Assessment area, plus they are supported by other professionals including: Engineers, a Pharmaceutical Chemist, Epidemiologists, and Health Services Administrators.

A report issued by the Technology Assessment Department is used to request assessments on other areas of the Public Health Ministry. Once all the reports of the areas involved are collected, a final report can be done, being the latter the fundamental decision-making tool for authorities.

## EXPERIENCE RESULTS AND ASSESSMENT

Below are the results of the assessments performed in the period July 2009 - August 2012.

Table 1 - Distribution of applications for incorporating health services according to Type of service and year. Period: July 2009 - August 2012

HEALTHCARE SERVICE	YEAR				TOTAL
	2009	2010	2011	2012	
Intensive Care Units	1	2	0	0	3
Hyperbaric Medicine Service	1	0	0	0	1
Specialized Medicine Services	2	1	2	0	5
Out-patient Services	1	4	4	3	12
Surgical Block	1	0	1	0	2
Clinical Analysis Laboratory	1	0	0	0	1
Imaging Service	0	0	1	0	1
Property Acquisition	2	0	0	0	2
Facility's expanding works	1	1	0	1	3
<b>TOTAL</b>	<b>10</b>	<b>8</b>	<b>8</b>	<b>4</b>	<b>30</b>

Source: Public Health Ministry (MSP).

Table 2 - Distribution of applications for incorporating medical devices according to Type of device and year. Period: July 2009 - August 2012

MEDICAL DEVICE	YEAR				TOTAL
	2009	2010	2011	2012	
C-arm	0	3	0	2	5
Hyperbaric Chamber	0	2	0	0	2
Anaesthetic Machine	2	2	0	0	4
Linear Accelerator	3	0	0	0	3
Angiographies	1	0	0	3	4
Extracorporeal circulation pump	1	0	0	0	1
Cobalt puma	0	1	0	1	2
Robotic Surgery equipment	0	2	0	0	2
Bone densitometry	1	0	0	0	1
Ultrasounds	2	2	0	4	8
Gamma cameras	1	0	0	0	1
Mammography	2	0	2	2	6
Radiology Conventional Equipment	3	6	2	0	11
Magnetic Resonance	4	2	4	2	12
CT Scanner	8	3	3	3	17
Positron emission CT Scanner	1	1	1	0	3
<b>TOTAL</b>	<b>29</b>	<b>24</b>	<b>12</b>	<b>17</b>	<b>82</b>

Source: Public Health Ministry (MSP).

Table 3 – Status of applications for incorporating technology. Period July 2009 – August 2012

	Total of applications	Approved	Under evaluation	Not approved
Medical devices	82	34	29	2
Health services	30	11	15	0

## Sanitary Surveillance: creation of the National Technosurveillance System<sup>IX</sup>

*Catherine Ausqui; Salomé Fernandez; Susana Novaro*

### INTRODUCTION

The importance of structuring a surveillance system for medical products is integral part of the need of ensuring the safety and effectiveness of these products once they go out into the market, as well to the need of meeting the compliance and commitment set by the Uruguay's Public Health Ministry (PHM) with the population.

A technosurveillance system refers to the structure, rules and activities that under the supervision of the health authority are intended to collect and evaluate systematically all information on adverse events and failures related to the use of medical devices; and set preventive recommendations to be applied in each case. Adverse events associated with medical devices in the post-marketing stage and the factors that may predispose their appearance, become a key issue in the surveillance and control activities conducted by the Uruguay's PHM, which must ensure that these products meet the safety and efficacy clinical conditions for which they were approved for sale in the country.

### OBJECTIVES

Establish mechanisms to collect, evaluate and manage all information related to safety and quality of medical devices, in order to take the necessary measures to protect the users' health and not waste resources dedicated to the health system<sup>20,21</sup>.

## METHODOLOGY, RESOURCES USED AND RESULTS

### Technosurveillance's implementation experience in Uruguay

The Technology Assessment Department has been receiving international alerts and notifications of national incidents since 2004. Then it contacts companies and services involved, thus proceeding to the case investigation and implementation of corrective actions.

In July 2006, a group of technicians were selected to design a Technosurveillance System capable of integrating all health institutions, companies, professionals and technicians into a notification network for adverse events related to medical equipment. In 2009 a Technological surveillance module, which allows to entry incidents over the Internet, was incorporated thanks to the initiatives undertaken by the Economy Ministry's Centralized Procurement Unit for the Grading System (SIGECALC).

Being the Pharmacovigilance the most traditional area with the largest systematization of processes in the country and the region, a close coordination with this unit began in 2010. It was based on the intention of standardizing processes that are very different from one area to another, and developing numerous joint training courses for health personnel during this last period.

The progress made puts us in position to ask ourselves about a stage of systematic recording of incidents by using different strategies for reporting and investigation of incidents, including the creation of Sentinel Centers. The implementation of a Technosurveillance System (TVG) that allows monitoring the performance of devices in health services results in strengthening the Health Ministry's regulatory role and police power, and a greater commitment, involvement and participation. We are in the first instance of the implementation of the Technosurveillance system and we can already see the positive effects of the actions taken.

Medical devices affected by Technosurveillance (TVG) activities correspond to the following categories:

- A. Diagnostic reagents
- B. Medical equipment
- C. Therapeutic devices

The Technosurveillance system is in our country comprises:

1. Authorities
  - a) National Health Ministry (MSP), Health Assessment Division - Technology Assessment Department (DET). This division includes the Technosurveillance Central Unit, made of a group of professionals that are responsible for managing the activities of the National Technosurveillance System, being the central node of the network.

The references for developing the surveillance function are:

- b) International Health Authorities: Regulatory Agencies for Medical Products (Anvisa, Anmat, ANSM, MHRA, FDA) Technology Assessment Agencies, regulatory bodies (Radiation Protection Regulatory Authority, in our country, etc).
2. Notifiers not included in the industry.

It includes all medical staff of institutions that provide health services (public and private providers in the country), the Highly Specialized Medicine Institutes (IMAE), independent professionals. Using the appropriate form they may notify the Technology Assessment Department and the marketing company the appearance of an adverse event. The main system's notifiers will be the Technosurveillance managers at the Sentinel Centers.
3. Medical Devices Industry

Includes nationwide manufacturers, importers, and distributors of medical devices, in addition to any natural or legal person that participates directly or indirectly in its marketing or distribution.

The regulation of our country provides specific obligations regarding Technosurveillance of these companies.
4. Other institutions

Includes other national organizations involved in the use of Medical Devices (PM), being them public or private (National Resources Fund, National Public Health Laboratory System, National Blood Service, National Regulatory Authority on Radiation Protection, etc.)
5. User/Patient

Includes individual users (inside and outside health institutions), as well as patients affected to medical devices.

Sentinel Centers are created to meet the need for obtaining reliable information on the performance of medical devices, being users of large quantities and diversity of products.

The network's member institutions are called Sentinel Centers and their activities are the following:

1. Designate a Technosurveillance unit within the structure of the service and have a health professional to act as Technosurveillance manager. This professional can also be a member of one of the existing committees linked to the recently created Patient Safety Committees.
2. Ensure the commitment of the Technical Departments of the institutions to all support actions related to surveillance.
3. Include surveillance activities as the Institution's goals on quality.
4. Provide a physical space and administrative support necessary to perform the actions.

## Technosurveillance Units at Sentinel Centers

In the general approach we are starting to implement, each unit will act as a link between the different areas involved in the use of health technologies, with the support of other related units, such as pharmacy, maintenance, materials center, according to the type of products used.

It was proposed for the Technosurveillance unit to identify, analyze, anticipate and report all events related to the use of equipment, devices and reagents during clinical practice.

Therefore, it should be linked to different areas such as:

- Management and Administration
- Maintenance
- Pharmacy
- Haemotherapy Service
- Purchasing, inventory sector, hospital supplies management
- Hospital infections committee
- Nursing
- Materials and sterilization Center
- Health team
- Architecture Division, among others

The Technosurveillance risk management is expected to be made of professionals with a comprehensive view of assistance and the use of medical devices. The primary member of the Technosurveillance Unit is the Technosurveillance Manager, who must have a proactive profile and be able to interact with the institution's different interface areas.

The institution should support Technosurveillance by communicating its importance to all health team members and facilitating the communication between the different members of the team with the manager and all the activities the latter proposes regarding the strengthening of the technosurveillance system.

### Technosurveillance Unit's Manager Profile

- It has been proposed to designate a professional of the institution itself. It is very important that this professional is fully integrated to the institution's daily activities and, in particular, it is desirable that his/her usual role includes being involved in processes related to the management of medical devices.
- Be a professional who is working in the Health area: Doctor of Medicine, Bachelor of Nursing, Nursing Assistant, Doctor of Odontology, Pharmaceutical Chemist, Biomedical Engineer, Clinical Biochemist, among others.

- It is advisable for the professional to be trained in Epidemiology, Public Health and/ or Health Services Administration.
- Availability of at least 6 hours per week to perform the actions required by Technosurveillance.
- Professional experience of at least 2 years in health services.
- Build good human relations with the health team and show teamwork skills.
- Initiative to propose activities that will strengthen the institution's Technosurveillance.

Among the activities to be performed by the manager are:

- Implement Technosurveillance management .
- Develop and encourage health technosurveillance activities within the institution.
- Conduct studies and surveys regarding the products to be monitored.
- Support the identification and investigation of adverse events and participate in the management of corrective actions.
- Conduct staff training and notify the staff on corrective actions.
- Notify the Technosurveillance central unit.
- Prepare reports of occurrences and corrective or preventive actions.

Other people could be designated for working at the unit to develop technosurveillance activities along with the Manager. They may be professionals or just administrative support employees.

The Technosurveillance Manager checks each event based on daily reports, stories or identifications of events, to then, along with the users, analyze the problem and identify its origin, thus confirming whether it started because of the methodology of use or because a material, product or equipment failure<sup>20,21</sup>.

This activity aims to solve a single health problem, which is in some way related to other individuals in the community and, therefore, may represent a risk to the population.

Stages of the process that is being implemented:

1. Data collection and preliminary analysis of information.
2. Preliminary notification to the Technosurveillance Central Unit.
3. Research: Analysis of information. Conclusion. Developing local report.
4. Interaction with the Technosurveillance Central Unit.
5. Final Report
6. Implementation of corrective action, if necessary.

We have proposed the research process to be properly registered in a named and numbered document. Likewise, it should collect copies of all documents, photos, notes written by the participants, inspection reports, samples, and information obtained in the investigation, as well as records and proof of actions taken and conclusions obtained.

## EXPERIENCE ASSESSMENT

According to an initial analysis of this strategy's implementation, the overview of the assessment on new technology incorporation in the context of Uruguay's new Health System seems to be useful for:

- Use as input the reports that are generated for deciding the authorization for investments in accordance with current regulations.
- Define specific device replacement national plans, according to rates on demographic, epidemiological and specific use, for each case.
- Provide technical support so that regional plans can be developed in coordination with the national plans.
- To systematize a general methodology for the analysis of the installed capacity of the high-tech medical equipment in the country and set a schedule for analysis. Each research experience is a learning process for either the technosurveillance managers to technosurveillance units and the regulated sector.

Finally, it should be remarked that in this context not only the technology incorporation assessment is used as a decision making tool, but the making of services catalogue, medical therapeutic form, and clinical practice guidelines also converge on the same goals of improving equity in terms of population's access, responding effectively to the health needs, providing quality services, achieving efficiency, ensuring the accessibility, quality, equity and universality.

Being the challenge the joint work between the different areas and actors that are part of the Health System, and the fundamental strategy that provides access to see the National Technosurveillance System's expected results as the tool for monitoring the performance of products related to health services, which results in strengthening the Public Health Ministry's regulatory role and police power.

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## NOTES

- I - Innovative experience presented by Luis Beingolea More (Coordinator of Epidemiological Surveillance and Environmental Health - ORAS CONHU ).
- II - Innovative experience presented by Marthelise Eersel (Director of Health - Suriname).
- III - Descendants of African slaves who fled the sugar plantations in Suriname during the 16<sup>th</sup>, 17<sup>th</sup>, and 18<sup>th</sup> centuries.
- IV- Innovative experience presented by Maria Tereza da Costa Oliveira (Surveillance and Information Manager - Municipal Health Secretariat of Belo Horizonte, Minas Gerais, Brazil).

- V - Innovative experience presented by Fabiano Geraldo Pimenta Júnior (Municipal Health Secretary - Municipal Health Secretariat of Belo Horizonte, Minas Gerais, Brazil).
- VI- Innovative experience presented by: Alice Alves de Souza, Claudia Passos Guimarães Rabelo, Daniella Guimarães Araujo, Maria de Fátima Ferreira Francisco, Rosaura Maria da Costa Hexsel (Anvisa - Brazil).
- VII - Innovative experience developed by Julieta Curbelo (Anmat - Argentina).
- VIII and IX- Innovative experiences presented by: Catherine Ausqui; Salomé Fernández, Susana Novaro (Public Health Ministry - Uruguay).



## X. Paths to advance: an agenda for the 21<sup>st</sup> Century

*Eduardo Hage Carmo  
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### INTRODUCTION

**O**ur region's social indicators, including those related to health, have improved, although we are situated on the “middle of the way” when compared to the advances of developed countries' populations. A double burden of health problems (or even triple burden) are found in the region, which is characterized by a persisting high charge of communicable diseases, though incidence and mortality of many have decreased, and, on the other hand, an increase in indicators of chronic diseases and violence.

The epidemiological profiles are heterogeneous among the nations, with a high inequity between population groups in the hinterland of the countries. The poorer and with less access to health services suffer more from the mentioned double (or triple) burden. In some areas, these problems are bigger still, due to access hardships, extreme poverty, huge influx of people, displacement due to political, environmental and social issues, as well as in border regions, where a great vulnerability is found.

This heterogeneity and inequality are associated to differences in the life conditions of the populations, which requires the approach of political, economical, environmental and social determinants in order to understand the changes in epidemiological profiles. Notwithstanding that, the interventions cannot be restricted to the health sector, though the access to effective health interventions must be promoted and developed (for examples, vaccines, drugs, medical devices, health services and food).

We note that there is a lack of international literature on the South American epidemiological situation as a region. The data is dispersed on webpages, countries' publications or in analyses of the Latin American and Caribbean region as a whole. In this sense, we hope the present publication may contribute to dimensioning the knowledge on this issue, as well as to fostering an increase in the scientific production and its exchange between health, training and research institutions in the region.

## HEALTH SURVEILLANCE IN SOUTH AMERICA

It is not possible to identify a single or even articulated approach and concept on health surveillance in the region, nor the existence of a regional policy in this matter. We note there are social, technological and educational interventions in the struggle against health problems, which are, as a whole, practices of health surveillance. ISAGS's publication "Health Systems in South America: challenges to universality, integrality and equity"<sup>1</sup> represented a wide mapping of these practices, while different objects and types of interventions of epidemiological, sanitary and environmental surveillances were identified in each of the region's countries. However, when the scientific production in South America was analysed on the health surveillance issue, as carried out in this publication<sup>1</sup>, which enabled an assessment of the contribution of training and research institutions and of the conceptual reflection of health institutions on the issue, the conclusion was that the production is scarce and concentrated in few countries.

This scenario was also discussed in the conclusions of the Workshop on "Health Surveillance Systems", organized by ISAGS in 2011. The need to establish a health surveillance policy was indicated, which should include conceptual frameworks enabling the definition of objectives to be attained jointly by the Member States of UNASUR.

One of the challenges posed to the construction of a health surveillance policy is the identification of practices unifying (or that permit the integration) of different components of such surveillance. For example, the risk approach is a strategy surveillances usually use or are challenged to use either in the identification of the health problem or in the adoption of intervention measures on the health problem, including risk communication.

In this context, the book "Health Systems in South America" has evidenced that, in many situations, national health institutions focus their priority care in disease and control, emphasizing the biological dimension, with insufficient epidemiological focus and scarcely directed on social determinants<sup>1</sup>. However, these institutions have been increasingly incorporating the use of social and thematic indicators in the definition of health policies and actions. In the last decades, the influence of the biological model in the health sector, as an expression of globalization in this field, has narrowed the relation between the productive sector and the widespread consumption available to the citizens that are new to the consuming market. The speed of the so-called innovations are or intend to be incorporated into our daily lives, including those referring to a consumerist lifestyle, introducing new products and services to be offered at the consumer market.

The incorporation of these technologies, including marketing that promotes consumption, also represents new risks. It is not only the classic epidemiological risk in the relation health-disease, but also the sanitary risk and the potential anthropic risk<sup>i</sup>. Nations' economic dependency on this development model increasingly linked uncritically to the adoption of the health project for all, has led to the amplified incorporation of new products and technologies. This incorporation doesn't consider the real needs in increasing the population's access to quality health systems. This adds a new fragility to universal health systems, which is compounded by the widened globalization of these issues. Nowadays, risks of modernity aren't the defined risks, obtained in classical probability. They are detached from space and time and must be thought as a possible damage difficult to foresee (for instance tobacco, nanotechnology and others).

Sanitary surveillance in particular is at the core of this contradiction, as it is related to the production sector and society through the negative vision related to the possibility of damage. Health and economy, employment and risk, need, consumption and protection to health – these relations must be more and more addressed and must point to health promotion, information and the population's education. This way, the asymmetry of knowledge is reduced and the innovation in health is demystified in the context of capitalist production, as object of consumption.

Thus, considering that modern society demands a State with solely regulating role and considering the globalized world disperses anthropic risks throughout the planet, it is fundamental that nations organize themselves in blocs so risk management is carried out in an integrated, consensual and, when possible, unified way<sup>3</sup>.

## **PROPOSALS TO ADVANCE IN THE CONSTRUCTION OF A HEALTH SURVEILLANCE AGENDA**

As seen in this publication, there are regional agenda of work in the field of health surveillance that can be found in UNASUR Health's Five-Year Plan. It establishes the priorities in the action of the countries in the region. However, as remarked in Chapter 6 "South American's Network of Health Surveillance and Response: creation, agenda and challenges", there were little advances in terms of effective work in the subject and some of the surveillances' issues are not included as strategic actions. For instance, the only issue dealt by some of the countries' sanitary surveillances, which is approached by the Technical Group on Health Surveillance, is related to health at international point of entry. Thus, the inclusion of strategic subjects, like proper risk management related to processes of incorporation/consumption of technologies at a global level in the terms suggested here still requires a sound debate in the region, as well as the establishment of consensuses and definition of intervention priorities.

Also, as seen in this publication's Chapter 9 "Innovating Experiences and Challenges for Health Surveillance", there are various experiences in the region's countries where simple and innovative solutions to tackle priority issues, many of which may be replicated in other countries after proper adaptations to local scenarios. Therefore, as stimulus to cooperation within the region and with other regions, there is the necessity to create opportunities to identify, systematize and share countries' experiences in the struggle against risks and health problems that are common to the region, with special emphasis to surveillance interventions.

Taking this scenario into consideration, as well as the need to invigorate joint work in the sanitary surveillance field, some proposals may be put forward, as concluded by the Workshops on Health Surveillance and on Sanitary Surveillance Systems in South America organized by ISAGS:

1. Establish a conceptual framework and a regional policy on health surveillance, capitalizing on existing South American countries' and networks' experiences and advances;
2. Support the strengthening of the works carried out by the South American Network of Health Surveillance and Response, fostering its integration with other groups and corresponding networks of UNASUR;
3. Develop multisectoral and intersectoral strategies in promotion, prevention and disease control actions;
4. Articulate the stakeholders' efforts towards the health sector's inner by convening key actors, general managements and advising bodies so as to integrally manage surveillance and response decisions in public health from operating to high-level decision-making levels, establishing primary health care and interculturality as paramount to a broad supporting and lasting base;
5. As there is an enormous turnover in health services' personnel, use adequate training tools and processes for professionals of all levels in the health system so as to complement health surveillance actions. A clear need for sound training in the human resources area was diagnosed, as means to train the health professional with a health surveillance perspective oriented to social determinants and cultural aspects that consider risk perception and respect its economic, political, social and cultural characteristics;
6. Use more cost-effective and scientifically evidenced health interventions and technologies, yet taking into account that health expenses must be considered health investment (in the context of the population). Also, it must be taken in consideration that the ratio cost/affected person must be analysed in its particular context for populations with more difficulties of access to health services;

7. Monitor and assess interventions in terms of effectiveness, with the dissemination of the generated knowledge in these evaluations throughout all countries. Dissemination strategies include: exchange of successful experiences, consolidation and dissemination of available information in the webpage of countries and international bodies (Pan-American Health Organization, MERCOSUR, Andean Health Organism – Hipolito Unanue Covenant), and publishing in scientific magazines of the region's countries;
8. Identify regional reference laboratories that may amplify the capacity of diagnosis and evaluation of the region's products conformity. Make use of existing strengths and define strategies and criteria to form a regional network (including sub-networks);
9. Considering successful collaboration experiences of the Pan-American Health Organization with countries and sub-regional blocs (MERCOSUR, ORASCONHU, Amazon Cooperation Treaty Organization), including topics like immunization, International Health Regulations (IHR), non-communicable diseases, and others, it is necessary to define strategies in order to continue this collaboration with the South American Network of Health Surveillance and Response. Therefore, the alignment with other regional and sub-regional agendas is proposed so as to avoid duplicity in technical work and foster the dissemination of successful experiences in the region;
10. Create interdisciplinary teams (not restricted to health professionals and including community leaders). The formation of transnational quick response teams is also proposed to be activated in public health emergencies in the region that require joint efforts, establishing mechanisms that ensure the timely travel for the personnel;
11. Incorporate new communication and information technologies so there is effective time for analysis in the quest for quality and opportunity response. Therefore, the development and use of the information systems and technologies (like VIGISAS) is proposed, so regional analyses can be carried out and health information can be shared among countries in support to decision-making;
12. Seek the integration of initiatives in both sides of the frontier, involving decision-making from local- to national-level. These initiatives include the identification of common problems, mapping of damages to health and risk factors, development of information systems or enhancement of the existing ones, in order to enable joint data analysis and the execution of joint interventions;
13. Make use of creative, innovative and appropriate strategies for each territory, especially in socially, economically and culturally interdependent populations, like, for instance, communitarian surveillance, ensuring long-term sustainability;

14. Support the articulation of the technical group on disaster risk management with other technical groups, especially the Groups on Health Surveillance and Response and on Social Determinants;
15. Define common indicators to analyse and monitor non-communicable diseases and its risk factors, using the advances developed by the networks (MERCOSUR and Andean Network on Epidemiological Surveillance).

In relation with the IHR implementation, which represented a milestone in the integration of regional sub-networks in the conformation of the Network on Health Surveillance and Response, a group of proposals for the region was elaborated: take the Regulations' implementation in the region's countries as an opportunity to identify breaches, elaborate and implement capacity development plans (other than basic ones); identify national strengths, which may be shared with other countries and form sub-networks (consider these strengths as regional public goods); defend a political assessment of the IHR implementation and ensure the allocation of necessary resources; make use of existing national political spaces for managing the IHR implementation, involving other sectors with defined responsibilities in the field; include sanitary surveillance actions in the national emergency plans, considering focuses related to risk prevention.

In relation to Sanitary Surveillance, it was noted that all UNASUR countries count with a legal framework for action in this field, even though, from an organizational point of view, the institutional arrangements are very diverse and, in general, disperse in different State organs and different hierarchy levels<sup>1</sup>.

Among the various issues and specific problems of sanitary surveillance that came up in the workshop on the subject, undoubtedly the medicines issue stood out, including concerns on costs, rational access and, mainly, the quality dimension.

Other issue that grew in importance and involves all the others is risk communication. It is unanimous that it is a complex and specific problem, as it comprehends deep technical knowledge. However, it has to be addressed in a multidisciplinary manner, taking in consideration the social, cultural, economic, historical aspects, because the field of sanitary surveillance doesn't include solely regulatory aspects. Transparency and reliability on institutions is another fundamental factor for successful communication and, consequently, for the acceptance of risk minimization proposals.

Envisioning a future problem points to the necessity of dealing with the so-called medical devices as an urgent issue to be addressed. However, this issue evidences the sanitary surveillance system's fragility when it comes to technological innovations and its incorporation to the health system. The regulation's fragility presents itself clearer, be it a result of the speed the novelties appear or a difficulty

the public system has to follow new knowledge, or the lack of human resources, or the old sanitary surveillance structures in quality control. Fragilities in the pre- and post-market actions come up strongly. So as to tackle the challenge, it is suggested at first a debate on technological incorporations, the so-called innovations that pressurize more and more the costs of the health sector. The recognition of international certifications and inspections, risk communication and a reasonable number of minimally qualified human resources must also serve as bases to the enormous work on sight.

To sum up, medical device could be a model framework of research in the UNASUR countries, because it is related to a tremendously strong market demand out of a privatising and capitalist rationale, which sees health and this sector's products as consumer goods associated to the State's deficiency in the instrumentalization of health protection and promotion. This could also be a model for the population's risk perception associating this desire for access with the impact on the funding system, tanking into account the adequate balance between associated risks and the benefits of its use.

These issues were also presented in the mentioned workshop, more or less intensely, depending on the product or service, and some proposals were presented, as follows:

1. The need to create or strengthen networks of specific action. Quality control of products moving in the region is an example. An efficient and integrated network would be fundamental, one able to act in laboratory analyses and to systematize reports (again, risk communication);
2. Elaboration of a regional pharmacopoeia in UNASUR incorporating local realities either from a technical or a cultural point of view;
3. Provide recognized and jointly elaborated reference materials. A policy for non-pharmacopoeia methodologies in the medicines field;
4. International certification for companies should be considered a priority for UNASUR, especially for producers of inputs considered strategic to each country. There is a clear need to get to a regional consensus on the issue, taking in consideration the various conflictive initiatives of many international organisms;
5. Getting to know and disseminating technology incorporation programmes being developed by some UNASUR countries can be a way to approach another component mentioned as limiting a bigger supply of health services: the price policy and its various components;

6. The knowledge of experiences in post-market monitoring, especially those linked to pharmacovigilance and technological surveillance is seen as another factor of aggregation, unification and collaboration. The outcomes could be an incentive policy to knowledge on risk communication of the population in general and a region's system of common use.

Taking the aforementioned propositions to boost health surveillance activities in the countries of South America in consideration, some possibilities for the collaboration of ISAGS can be imagined through the dissemination of existing experiences in the countries. For instance, everything related to the points of the agenda on health surveillance where the technical groups haven't progressed much or in which there is little regional experience developed. These activities must be developed along with UNASUR technical groups or networks, and must go through necessary debates in order to face the challenges identified here for the health surveillance area.

ISAGS can also support the consolidation and knowledge production on the epidemiological changes in the region and on the existing capacities in the health surveillance areas of the countries.

Finally, as a fundamental framework for the cooperation proposed for ISAGS in the health surveillance issue, this Institute may support the region's countries in the formulation of a regional health surveillance policy, defining concepts and functions, and identifying necessary articulations for health surveillance in the region.

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## NOTES

- I- See the introductory chapter of this publication "Conception and Practices of Surveillance in the South American Health Systems".

South America presents important particularities in its historical, social and political formation. It is also a geographical space containing deep structural heterogeneities requiring the development of integrating policies that must, nonetheless, take such differences in consideration. Representatives of the member countries of the Union of South American Nations (Unasur) had this challenge in mind when, in 2009, they proposed to the South American Health Council an agenda taking health as a fundamental right, vital for human and social development. As a booster for the integration of the nations, health must contribute to asymmetry reduction among the region's countries. In this sense, the policies and actions of surveillance systems are fundamental.

Taking this perspective, Isags organized two thematic workshops that led to the collective debate on national experiences and the identification of main issues in the countries of the region, whilst introducing a discussion of the surveillance systems' signalled challenges in a context of deep changes in epidemiological patterns.

Isags second book materializes the proposal of a publication comprising health surveillance in different fields, perspectives and practices, which are part of the region's diversity. Thus, its main contribution is the consolidation of critical and political knowledge on the South American health surveillance systems, from an integral point-of-view articulating environmental, epidemiological and sanitary surveillance.

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